B BRAUN

Konformitätserklärung

Declaration of Conformity

Document-No.:	**084-001 (1)**
Revision-No.:	**2**
Effective Date:	**Last date of signature**
Page:	**1 of 4**

Wir

We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

erklären in eigener Verantwortung,
dass das/die Produkt/e

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Handschuh, chirurgisch, steril

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

(1)
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte,
geändert durch Richtlinie 2007/47/EG

Konformitätsbewertungsverfahren
nach Anhang II
ohne Abschnitt 4
der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123

hereby declare in our own responsibility
that the product/s

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Gloves, surgical, sterile

(article numbers see attachment I)

is/are in compliance with the following directive

(1)
Council Directive 93/42/EEC of 14 June 1993
concerning Medical Devices,
amended by Directive 2007/47/EG

Conformity assessment procedure
according to annex II
without part 4
of the Directive named above

Classification
according to annex IX of the Directive named above:
Class IIa

Notified body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

sowie

(2)
in den einschlägigen Anforderungen der Verordnung (EU) 2016/425 des Europäischen Parlaments und des Rates vom 09.03.2016 über persönliche Schutzausrüstung

Klassifizierung
Kategorie III (hohes Risiko)

Benannte Stelle
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Ireland
Kennnummer 2777

Datum der ersten CE-Kennzeichnung
1996-10

Gültig bis
2024-05-26

and

(2)
relevant requirements of the Regulation (EU) 2016/425 of the European Parliament and of the council of 09.03.2016 on personal protective equipment

Classification
Category III (high risks)

Notified body
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Ireland
Identification number 2777

Date of first CE-marking
1996-10

Valid until
2024-05-26

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product Name	Klasse / Class	Kategorie/ Category
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III
6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III

6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III
6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Декларация за съответствие

Ние,

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Германия

с настоящото декларираме на собствена отговорност, че продуктът/ите

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Ръкавици, хирургични, стерилни

(за каталожните номера вж. приложение I)

съответства/т на следните директиви

(1)

Директива на Съвета 93/42/ЕИО от 14 юни 1993 г.
относно медицинските изделия, изменена с Директива 2007/47/ЕО

Процедура за оценяване на съответствието
съгласно приложение II
без част 4
от горепосочената Директива

Класификация
съгласно приложение IX от горепосочената Директива:
Клас IIa

Нотифициран орган
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Германия
Идентификационен номер 0123

и

(2)

съществените изисквания на Регламент (ЕС) 2016/425 на Европейския парламент и на Съвета от 09.03.2016 г. относно личните предпазни средства

Класификация
Категория III (висок риск)

Нотифициран орган
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Ирландия
Идентификационен номер 2777

Дата на първата маркировка CE
1996-10

Настоящата декларация за съответствие е валидна до
2024-05-26

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management
Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs
OPM Germany

Приложение I

Кат. №	Наименование на продукта	Клас	Категория
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III

6080990LAT	Vasco® OP Sensitive	IIa	III
6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III

6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III
6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Declaración de conformidad

La empresa

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Alemania

declara bajo su exclusiva responsabilidad la conformidad de los siguientes productos:

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
guantes, quirúrgicos, estériles

(véanse los números de los artículos en el anexo I)

con las directivas actualmente en vigor

(1)
Directiva 93/42/CEE del Consejo de 14 de junio de 1993
relativa a los productos sanitarios ,
modificada por la Directiva 2007/47/CE

Procedimiento de evaluación de la conformidad
de acuerdo con el anexo II
sin la parte 4
de la directiva arriba indicada

Clasificación
conforme al anexo IX de la directiva arriba indicada:
Clase IIa

Organismo notificado
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Múnich
Alemania
Número de identificación 0123

y

(2)

prescripciones aplicables del Reglamento (UE) 2016/425 del Parlamento Europeo y del Consejo de 9 de marzo de 2016 relativo a los equipos de protección individual

Clasificación
Categoría III (alto riesgo)

Organismo notificado
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Irlanda
Número de identificación 2777

Fecha del primer marcado CE
1996-10

La presente declaración de conformidad es válida hasta el
2024-05-26

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Anexo I

N.º art.º	Nombre de producto	Clase	Categoría
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III

6080990LAT	Vasco® OP Sensitive	IIa	III
6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
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6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III

6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III
6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Vastavusdeklaratsioon

K

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Saksamaa

kinnitab käesolevaga oma ainuvastutust selle eest, et toode (tooted):

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Kindad, kirurgilised, steriilsed

(toote numbrit vt lisast I)

on kooskõlas järgmiste direktiividega

(1)

Nõukogu direktiiv 93/42/EMÜ 14. juunist 1993
meditsiiniseadmete kohta, muudetud direktiiviga 2007/47/EÜ

Vastavuse hindamisprotseduur
vastavalt lisale II
ilma 4. osata
ülalnimetatud direktiivist

Klassifikatsioon
vastavalt ülalnimetatud direktiivi lisale IX:
Klass IIa

Teavitatud asutus
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Saksamaa
Identifitseerimisnumber 0123

ja

(2)

Euroopa Parlamendi ja nõukogu 09.03.2016 määruse (EL) 2016/425 asjakohased nõuded isikukaitsevahendite kohta

Vastavusdeklaratsioon

Klassifikatsioon
Kategooria III (kõrge risk)

Teavitatud asutus
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Iirimaa
Identifitseerimisnumber 2777

Esmase CE-märgise kuupäev
Oktoober 1996

Käesolev vastavusdeklaratsioon on kehtiv kuni
26.05.2024

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Lisa I

Toote nr	Toote nimetus	Klass	Kategooria
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III

6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III

6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Déclaration de conformité

Nous

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Allemagne

déclarons par les présentes, dans les limites de nos responsabilités
que le(s) produit(s)

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Gants, chirurgicaux, stériles

(références d'article, voir annexe I)

est/sont conforme(s) aux directives suivantes

(1)

Directive 93/42/CEE du Conseil du 14 juin 1993
relative aux Dispositifs Médicaux,
modifiée par la Directive 2007/47/EG

Procédure d'évaluation de la conformité
selon l'annexe II
à l'exclusion de la partie 4
de la Directive citée ci-dessus

Classification
selon l'annexe IX de la Directive citée ci-dessus :
Classe IIa

Organisme notifié
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Allemagne
Numéro d'identification 0123

et

(2)

exigences pertinentes du règlement (UE) 2016/425 du Parlement européen et du Conseil du 09/03/2016 relatif aux équipements de protection individuelle

Classification
Catégorie III (risque élevé)

Organisme notifié
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Irlande
Numéro d'identification 2777

Date du premier marquage CE
1996-10

La présente Déclaration de conformité est valide jusqu'au
2024-05-26

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management
Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs
OPM Germany

Annexe I

Référence d'article	Nom du produit	Classe	Catégorie
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III

Déclaration de conformité

6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III

Déclaration de conformité

6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Vaatimustenmukaisuusvakuutus

Me,

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Německo,

vakuutamme täten omalla vastuullamme,
että tuotteet

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Käsineet, kirurgiset, steriilit

(ks. tuotenumerot liitteestä I)

täyttävät seuraavan direktiivin vaatimukset:

(1)

Neuvoston direktiivi 93/42/ETY, annettu 14 päivänä kesäkuuta 1993,
lääkinnällisistä laitteista,
sellaisena kuin se on muutettuna direktiivillä 2007/47/EY

Vaatimustenmukaisuuden arviointimenettely
liitteen II mukainen
ilman osaa 4
edellä mainitun direktiivin

Edellä mainitun direktiivin liitteen IX mukainen luokitus:

Luokka Iia

Ilmoitettu laitos
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Saksa
Ilmoitetun laitoksen numero 0123

ja

(2)
henkilönsuojaimista 9 päivänä maaliskuuta 2016 annetun Euroopan parlamentin ja neuvoston asetuksen (EU) 2016/425 sovellettavat vaatimukset

Luokitus
III luokka (suuri riski)

Ilmoitettu laitos
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Irlanti
Ilmoitetun laitoksen numero 2777

Ensimmäisen CE-merkinnän päivämäärä
1996-10

Voimassa:
26.5.2024 asti

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management
Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs
OPM Germany

Liite I

Tuotenro	Tuotenimi	Luokka	Luokitus
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III

6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III

6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Izjava o sukladnosti

Mi

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Njemačka

pod vlastitom odgovornošću izjavljujemo
da je proizvod

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Rukavice, kirurške, sterilne

(za brojeve proizvoda pogledajte Prilog I.)

sukladan sa sljedećim direktivama:

(1)
Direktivom Vijeća 93/42/EEZ od 14. lipnja 1993.
o medicinskim proizvodima,
kako je izmijenjena Direktivom 2007/47/EZ

Postupak ocjenjivanja sukladnosti
u skladu s Prilogom II.
bez dijela 4.
gore navedene Direktive

Razvrstavanje
u skladu s Prilogom IX. gore navedene Direktive:
klasa rizika II.a

Prijavljeno tijelo
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Njemačka
Identifikacijski broj 01230

i

(2)

relevantni zahtjevi Uredbe (EU) 2016/425 Europskog parlamenta i vijeća od 09.03.2016. o osobnoj zaštitnoj opremi

Razvrstavanje
Kategorija III (visoki rizik)

Prijavljeno tijelo
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Irska
Identifikacijski broj 2777

Datum prve CE oznake sukladnosti
10. 1996.

Ova Izjava o sukladnosti vrijedi do
26. 5. 2024.

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Prilog I.

Broj proizvoda	Naziv proizvoda	Klasa rizika	Kategorija
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III

6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III

6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Megfelelőségi nyilatkozat

Mi, a

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Németország

saját felelősségünkre kijelentjük,
hogy az alábbi termék(ek)

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Kesztyű, sebészeti, steril

(a cikkszámok az I. függelékben találhatók)

megfelel(nek) az alábbi irányelveknek

(1)

az 1993. június 14-én kelt, az orvostechnikai eszközökről szóló,
a 2007/47/EK irányelvvel módosított
93/42/EGK tanácsi irányelvnek

Megfelelőség-értékelési eljárás
a fenti irányelv
4. rész nélküli
II. melléklete szerint

Osztályozás
a fenti irányelv IX. melléklete szerint:
Class IIa

Bejelentett szervezet
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Németország
Azonosító szám: 0123

és

Megfelelőségi nyilatkozat

(2)

a 2016. március 9-i, az egyéni védőeszközökről szóló 2016/425/EU Európai Parlamenti és Tanácsi rendelet megfelelő követelményei

Osztályozás
Kategória III (magas kockázat)

Bejelentett szervezet
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Írország
Azonosító szám: 2777

Az első CE-jelölés dátuma
1996.10.

A jelen Megfelelőségi nyilatkozat az alábbi időpontig érvényes:
2024.05.26.

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

I. függelék

Cikkszám	Terméknév	Osztály	Kategória
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
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6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III

6080990LAT	Vasco® OP Sensitive	IIa	III
6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III

Megfelelőségi nyilatkozat

6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III
6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Dichiarazione di conformità

Noi

B. Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen
Germania

dichiariamo con la presente, sotto la nostra responsabilità,
che il/i prodotto/i

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Guanti, chirurgici, sterili

(per i codici articolo vedere l'allegato I)

è/sono conforme/i alle seguenti direttive

(1)

Direttiva del consiglio 93/42/CEE del 14 giugno 1993
relativa ai dispositivi medicali,
emendata dalla Direttiva 2007/47/CE

Procedura di valutazione della conformità
in conformità all'allegato II
senza la parte 4
della Direttiva sopra indicata

Classificazione
in conformità all'allegato IX della Direttiva sopra indicata:
Classe IIa

Ente notificato
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Monaco
Germania
Numero di identificazione 0123

e

(2)

requisiti pertinenti del Regolamento (UE) 2016/425 del Parlamento europeo e del Consiglio del 09.03.2016 sui dispositivi di protezione individuale

Classificazione
Categoria III (alto rischio)

Ente notificato
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Irlanda
Numero di identificazione 2777

Data del primo marchio CE
1996-10

La presente Dichiarazione di conformità è valida fino al
26-05-2024

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Allegato I

Cod. articolo	Nome prodotto	Classe	Categoria
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
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6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III

6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
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6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
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6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
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6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III

6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Atitikties deklaracija

Mes,

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Vokietija

atsakingai pareiškiame, kad gaminys (-iai)

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Pirštinės (chirurginės, sterilios)

(gaminio numerius žr. I priede)

atitinka toliau nurodytas direktyvas

(1)
1993 m. birželio 14 d. Tarybos direktyvą 93/42/EEB
dėl medicinos prietaisų,
iš dalies pakeistą 2007/47/EB direktyva,

Atitikties vertinimo procedūra
pagal minėtosios Direktyvos
II priedą,
išskyrus 4 dalį

Klasifikacija
pagal minėtosios Direktyvos IX priedą:
IIa klasė

Notifikuotoji įstaiga
„TÜV SÜD Product Service GmbH“
Ridlerstraße 65
80339 München
Vokietija
Identifikacijos numeris 0123

ir

Atitikties deklaracija

(2)

taikomi reikalavimai pagal 2016-03-09 Europos Parlamento ir Tarybos Reglamentą (EB) Nr. 2016/425 dėl asmeninių apsaugos priemonių

Klasifikacija
Kategorija III (didelė rizika)

Notifikuotoji įstaiga
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Airija
Identifikacijos numeris 2777

Pirmojo CE ženklinimo data
1996-10

Ši atitikties deklaracija galioja iki
2024-05-26

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

I priedas

Gam. Nr.	Gaminio pavadinimas	Klasė	Kategorija
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III

6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III
6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III

6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III
6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Atbilstības deklarācija

Mēs,

B. Braun Melsungen AG,
Carl-Braun-Straße 1,
34212 Melsungen,
Vācija,

ar šo, uzņemoties atbildību, apstiprinām,
ka produkts/-i:

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
cimdi, ķirurģijas produkti, sterili produkti

(produktu numurus skatiet I pielikumā)

atbilst tālāk tekstā minētajām direktīvām.

(1)

Padomes Direktīva 93/42/EEK (1993. gada 14. jūnijs)
par medicīnas ierīcēm,
kurā grozījumi izdarīti ar Direktīvu 2007/47/EK

Atbilstības novērtējuma procedūra
saskaņā ar iepriekš tekstā minētās Direktīvas
II pielikumu,
neskaitot 4. daļu

Klasifikācija
saskaņā ar iepriekš tekstā minētās Direktīvas IX pielikumu:
IIa klase

Pilnvarotā iestāde
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Vācija
Identifikācijas numurs 0123

un

Atbilstības deklarācija

(2)

Eiropas Parlamenta un Padomes Regula (ES) 2016/425 (2016. gada 9. marts) par individuālajiem aizsardzības līdzekļiem

Klasifikācija
Kategorija III (augsts riska līmenis)

Pilnvarotā iestāde
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Īrija
Identifikācijas numurs 2777

Datums, kad pirmo reizi marķēts ar CE zīmi,
1996.10

Šī Atbilstības deklarācija ir spēkā līdz
2024.05.26

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Atbilstības deklarācija

I pielikums

Prod. Nr.	Produkta nosaukums	Klase	Kategorija
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
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6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
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6081324LAT	Vasco® OP eco	IIa	III
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6081375LAT	Vasco® OP eco	IIa	III
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9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III

6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
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6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
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6035848	Vasco® Surgical Micro	IIa	III
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6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
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6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III

6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Verklaring van overeenstemming

Wij

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Duitsland

verklaren hierbij onder eigen verantwoordelijkheid
dat het product/de producten

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
handschoenen, chirurgisch, steriel

(zie bijlage I voor de artikelnummers)

in overeenstemming is/zijn met de volgende richtlijnen

(1)

Richtlijn 93/42/EEG van de Raad van 14 juni 1993
betreffende medische hulpmiddelen,
gewijzigd bij Richtlijn 2007/47/EG

Overeenstemmingsbeoordelingsprocedure
volgens bijlage II
zonder deel 4
van de hierboven genoemde richtlijn

Classificatie
overeenkomstig bijlage IX van de hierboven genoemde richtlijn:
Klasse IIa

Aangemelde instantie
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Duitsland
Identificatienummer 0123

en

(2)

relevante eisen van Verordening (EU) nr. 2016/425 van het Europees Parlement en de Raad van 09.03.2016 betreffende persoonlijke beschermingsmiddelen

Classificatie
Categorie III (hoog risico)

Aangemelde instantie
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Ierland
Identificatienummer 2777

Datum van eerste CE-markering
1996-10

Deze verklaring van overeenstemming is geldig tot
26-05-2024

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Bijlage I

Art. nr.	Productnaam	Klasse	Categorie
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
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6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III

6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
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6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
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6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
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6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
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6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III

6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Samsvarserklæring

Vi

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Tyskland

erklærer herved på eget ansvar
at produktet/produktene

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Hansker, kirurgiske, sterile

(se vedlegg I for artikkelnr.)

er i samsvar med følgende direktiver

(1)

Rådsdirektiv 93/42/EØF av 14. juni 1993
om medisinsk utstyr,
endret ved direktiv 2007/47/EF

Prosedyre for vurdering av samsvar
i samsvar med vedlegg II
med unntak av del 4
i direktivet som er angitt ovenfor

Klassifisering
i samsvar med vedlegg IX i direktivet som er angitt ovenfor:
Klasse IIa

Tilsynsorgan
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Tyskland
Identifikasjonsnummer 0123

og

(2)

relevante krav i EU-bestemmelsen 2016/425 fra Europaparlamentet og fra rådet den 9. mars 2016 om personlig verneutstyr

Klassifisering
Kategori III (høy risiko)

Tilsynsorgan
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Irland
Identifikasjonsnummer 2777

Dato for første CE-merking
1996-10

Denne samsvarserklæringen er gyldig til
26.05.2024

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Samsvarserklæring

Vedlegg I

Artikkelnr.	Produktnavn	Klasse	Kategori
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
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6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III
6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III

6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III
6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Deklaracja zgodności

Firma

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Niemcy

niniejszym oświadcza na własną odpowiedzialność,
że produkt(-y)

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
rękawice chirurgiczne jałowe

(numery artykułów dostępne w załączniku I)

jest/są zgodny/e z poniższymi dyrektywami

(1)
Dyrektywa Rady 93/42/EWG z dnia 14 czerwca 1993 r.
dotycząca wyrobów medycznych,
zmieniona dyrektywą 2007/47/WE

Procedura oceny zgodności
zgodnie z załącznikiem II
bez części 4
do wyżej wymienionej dyrektywy

Klasyfikacja
zgodnie z załącznikiem IX do wyżej wymienionej dyrektywy:
Klasa IIa

Jednostka notyfikowana
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Niemcy
Numer identyfikacyjny 0123

oraz

(2)

odpowiednie wymogi rozporządzenia Parlamentu Europejskiego i Rady (UE) 2016/425 z dnia 9 marca 2016 r. w sprawie środków ochrony indywidualnej

Klasyfikacja
Kategoria III (wysokie ryzyko)

Jednostka notyfikowana
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Irlandia
Numer identyfikacyjny 2777

Data pierwszego przyznania oznakowania CE
1996-10

Niniejsza deklaracja zgodności obowiązuje do
2024-05-26

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management
Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs
OPM Germany

Załącznik I

Nr art.	Nazwa produktu	Klasa	Kategoria
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III

6080990LAT	Vasco® OP Sensitive	IIa	III
6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III

6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III
6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Declaração de conformidade

Nós

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Alemanha

pelo presente, declaramos, sob nossa exclusiva responsabilidade,
que o(s) produto(s)

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Luvas, cirúrgicas, estéreis

(números dos artigos, ver o anexo I)

está/estão em conformidade com as seguintes directivas:

(1)

Directiva do Conselho 93/42/CEE, de 14 de Junho de 1993,
relativa a dispositivos médicos,
alterada pela Directiva 2007/47/CE

Procedimento de avaliação da conformidade
de acordo com o anexo II
sem a secção 4
da Directiva supracitada

Classificação
de acordo com o anexo IX da Directiva supracitada:
Classe IIa

Organismo notificado
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Alemanha
Número de identificação 0123

e

Declaração de conformidade

(2)

requisitos relevantes do Regulamento (UE) 2016/425 do Parlamento Europeu e do Conselho de 09.03.2016 relativo aos equipamentos de proteção individual

Classificação
Categoria III (risco elevado)

Organismo notificado
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Irlanda
Número de identificação 2777

Data da primeira marcação CE
10-1996

Esta Declaração de Conformidade é válida até
26-05-2024

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Anexo I

N.º do art.	Nome do produto	Classe	Categoria
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III

6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III

6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Declarație de conformitate

Subscrisa

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germania

declarăm prin prezenta, pe propria răspundere,
că produsul/produsele

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Mănuși chirurgicale, sterile

(pentru numerele articolelor vezi anexa I)

respectă următoarele directive

(1)
Directiva Consiliului 93/42/CEE din data de 14 iunie 1993
privind dispozitivele medicale,
modificată prin Directiva 2007/47/CE

Procedura de evaluare a conformității
conform anexei II
exceptând partea 4
la Directiva menționată mai sus

Clasificare
conform anexei IX la Directiva menționată mai sus:
Clasa IIa

Organism notificat
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germania
Număr de identificare 0123

și

(2)

cerințe relevante ale Regulamentului (UE) 2016/425 al Parlamentului European și al Consiliului din 09.03.2016 privind echipamentele individuale de protecție

Clasificare
Categoria III (risc crescut)

Organism notificat
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Irlanda
Număr de identificare 2777

Data primului marcaj CE
1996-10

Prezenta Declarație de conformitate este valabilă până la
2024-05-26

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Anexa I

Nr. art.	Denumirea produsului	Clasa	Categoria
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III
6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III

6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III
6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Vyhlásenie o zhode

Spoločnosť

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Nemecko

týmto vyhlasuje,
že produkt/y

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Rukavice, chirurgické, sterilné

(čísla položiek sú uvedené v prílohe I)

je/sú v súlade s týmito smernicami

(1)

Smernica Rady 93/42/EHS zo 14. júna 1993
o zdravotníckych pomôckach,
zmenená smernicou 2007/47/ES

Postup posudzovania zhody
podľa prílohy II
bez časti 4
smernice uvedenej vyššie

Klasifikácia
podľa prílohy IX smernice uvedenej vyššie:
Trieda IIa

Notifikovaný orgán
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Nemecko
Identifikačné číslo 0123

a

(2)

príslušné požiadavky nariadenia Európskeho parlamentu a Rady (EÚ) 2016/425 z 9. marca 2016 o osobných ochranných prostriedkoch

Klasifikácia
Kategória III (vysoké riziko)

Notifikovaný orgán
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Írsko
Identifikačné číslo 2777

Dátum prvého označenia CE
10.1996

Toto vyhlásenie o zhode platí do
26.05.2024

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Príloha I

Č. položky	Názov produktu	Trieda	Kategória
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III

6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III
6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
6081200LAT	Vasco® OP Underglove	IIa	III
6081218LAT	Vasco® OP Underglove	IIa	III
6081226LAT	Vasco® OP Underglove	IIa	III
6081234LAT	Vasco® OP Underglove	IIa	III
6081242LAT	Vasco® OP Underglove	IIa	III
6081259LAT	Vasco® OP Underglove	IIa	III
6081267LAT	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III
6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III

6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Uygunluk Beyanı

Biz

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Almanya

olarak, sorumluluğu bize ait
olmak üzere

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Cerrahi, steril, eldiven

ürününün/ürünlerinin (parça numaraları için ek I'e bakınız)

aşağıdaki direktiflere uygun olduğunu beyan ederiz:

(1)
2007/47/EG sayılı Direktifle değiştirilen şekilde
Tıbbi Cihazlarla ilgili
14 Haziran 1993 tarihli 93/42/EEC sayılı Konsey Yönergesi

Yukarıda belirtilen Direktifin
dördüncü maddesi olmadan
ek II'ye göre
uyumluluk değerlendirme prosedürü

Yukarıda belirtilen Direktifin Ek IX bölümüne göre
Sınıflandırma:
Sınıf IIa

Onay kuruluşu
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Almanya
Tanımlama numarası 0123

ve

(2)

Avrupa Parlamentosu ve konseyinin 09.03.2016 tarihli ve (EU) 2016/425 sayılı kişisel koruyucu ekipmanla ilgili yönetmeliğinin ilgili gereksinimleri

Sınıflandırma
Kategori III (yüksek risk)

Onay kuruluşu
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
İrlanda
Tanımlama numarası 2777

İlk CE işareti tarihi
10-1996

Bu Uygunluk Beyanı şu tarihe kadar geçerlidir:
26-05-2024

Melsungen, 2020-01-08

i. V.

Thomas Möller
Vice President Quality Management Systems & Quality Compliance

Melsungen, 2020-01-08

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Ek I

Parça No.	Ürün Adı	Sınıf	Kategori
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
6081308LAT	Vasco® OP eco	IIa	III
6081316LAT	Vasco® OP eco	IIa	III
6081324LAT	Vasco® OP eco	IIa	III
6081332LAT	Vasco® OP eco	IIa	III
6081340LAT	Vasco® OP eco	IIa	III
6081359LAT	Vasco® OP eco	IIa	III
6081367LAT	Vasco® OP eco	IIa	III
6081375LAT	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
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9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
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6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6080990LAT	Vasco® OP Sensitive	IIa	III
6081002LAT	Vasco® OP Sensitive	IIa	III
6081010LAT	Vasco® OP Sensitive	IIa	III

6081029LAT	Vasco® OP Sensitive	IIa	III
6081037LAT	Vasco® OP Sensitive	IIa	III
6081045LAT	Vasco® OP Sensitive	IIa	III
6081053LAT	Vasco® OP Sensitive	IIa	III
6081060LAT	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6081199LAT	Vasco® OP Underglove	IIa	III
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6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
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6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III
6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III