# Declaration of Conformity

for the Patient waste containers

**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices**

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

| | |
|---|---|
| **General Product Name:** | Patient waste containers. |
| **Legal Manufacturer:** | Siam Intermagnate Co., Ltd. 138 Romklao Rd, Klongsampraved, Ladkrabang, Bangkok 10520, Thailand. |
| **Manufacturers SRN:** | TH-MF-000003828 |
| **Basic UDI-DI:** | 885642200003GM |
| **Variants:** | As per Appendix II (This document) – Product Listing/Schedule |
| **Intended Purpose:** | Containers for patient waste and other similar applications when these are being used for clinical procedures as define in the Product Summary and Classification Rational Document CS 03. |
| **MDR Classification:** | Class I [Rule 1] |
| **Notified Body:** | Not applicable for Class I (non-sterile, non-measuring function, non-reusable surgical instrument). |
| **EC Certificate:** | Not Applicable. |
| **EU Authorised Representative:** | Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta. |
| **EU Authorised Representative SRN:** | MT-AR-000000234 |
| **Medical Device Regulation Assessment Route:** | Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745. |

**Name** Akarapas Suppanukul **Position** Managing Director

**Signed**  **Date** 18-Nov-2022 **Place** Thailand

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party

**Appendix I – Applicable Standards**

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

| Standard/CS/Document Name | Description |
|---|---|
| 2017/745 | Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices |
| EN 1041:2008 | Information supplied by the manufacturer of medical devices |
| EN ISO 13485:2016 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971:2019 | Medical Devices – Application of Risk Management to Medical Devices |
| EN ISO 15223-1: 2021 | EN ISO 15223-1: 2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1: 2021) |

**Appendix II – Product Listing/Schedule**

| Part Number | Description/Name | GMDN Code |
|---|---|---|
| 0101 | Adult bedpan | 34867 |
| 0102 | Cover for adult bedpan | |
| 0103 | Round bedpan with cover | |
| 0104 | Child bedpan | |
| 0111, 0112 | Adult bedpan with two hollow handles | |
| 0113, 0114 | Adult bedpan with one hollow handle | |
| 0105, 0106 | Fracture bedpan | |
| 0107, 0108 | Male urinal | 40504 |
| 0109 | Female urinal | |
| 0261, 0264, 0267, 0270, 1201, 1202, 1203,1204, 1205, 1206, 1207, 1208, 1209 | Emesis basin | 11522 |
| 0262, 0265, 0268, 0271 | Cover for emesis basin | |
| 0301, 0302, 0303, 0304, 0305 | Sponge bowl | 42893 |
| 0331, 0332, 0333, 0334, 0335 | Lotion bowl | |
| 0321, 0322, 0323, 1228, 1229, 1230, 1231 | Wash basin | |
| 1254, 1255 | Waste can | |
| 8002, 8003 | Bucket | |
| 1223, 1224, 1225, 1226, 1227 | Petri dish | |
| 0110 | Irrigator | |

## Version History

| Version | Compiled by | Date | Description |
|---|---|---|---|
| 1 | John Adcock | 19 January 09 | First issue |
| 2 | Punnapoj P. | 14 December 09 | See Memo PP-14/12/09-01 |
| 3 | Punnapoj P. | 11 July 13 | See Memo PP-11/07/13-01 |
| 4 | Akarapas S. | 6 August 2014 | See Memo PP-06/08/14-01 |
| 5 | Akarapas S. | 5 November 2016 | See Memo PP-05/11/16-01 |
| 6 | Akarapas S. | 30 November 2018 | See Memo PP-30/11/18-01 |
| 7 | Akarapas S. | 28 November 2019 | See Memo PP-28/11/19-01 |
| 8 | Akarapas S. | 23 January 2020 | See Memo PP-23/01/20-01 |
| 9 | Akarapas S. | 18 February 2020 | See Memo PP-18/02/20-01 |
| 10 | Akarapas S. | 24 February 2020 | See Memo PP-24/02/20-01 |
| 11 | Akarapas S. | 02 June 2021 | To comply with MDR 2017/745 |
| 12 | Akarapas S | 18 November 2022 | Update post-market clinical follow-up plan and post-market clinical follow-up Evaluation report. |