TF Number: TF-03

# EU DECLARATION OF CONFORMITY

**In accordance with annex IV of the EU Medical Device Regulations EU 2017/745**

**This declaration is made under the sole responsibility of the legal manufacturer**

| **Medical device / medical device family:** | **Trinity Gold Gelling & Odour Control Sachets – Super Absorbent** | | |
|---|---|---|---|
| **Legal manufacturer:** | Trinity Healthcare Group A.S.<br>Sustekova 3697/49, 85104, Bratislava, Slovakia.<br>Registered in Slovakia No: 56185782 | | |
| **Single registration number: (SRN)** | SK-MF-000045565 | | |
| **Ref code(s) / Catalogue number(s)** | TR305 | **Basic UDI product identifiers** | 5061066300041 |
| **Intended purpose:** | Gel the contents of an ileostomy pouch. Reduce odour. | | |
| **Risk classification per annex VIII** | Class 1 Non-sterile, Non-measuring, Non-reusable, Non-custom made | | |
| **Medical device conformity assessment procedure undertaken:** | Manufacturer self-certification through issuance of an EU Declaration of Conformity in accordance with Article 19 of the Medical Device Regulation, having acted in accordance with the technical documentation requirements of Annexes II and III. | | |
| **Harmonised / Common Standards used** | See page 2 | | |

These devices are covered by the present declaration and are in conformity with this Regulation

**Place and date of issue of the declaration:**

**Date:** 09/01/2025 **City:** Bratislava

**Signed by:** lloyd pearce Digitally signed by lloyd pearce Date: 2025.01.09 12:57:07 +01'00'

Mr. L. Pearce

**Function:** Chief Executive Officer

**On behalf of Trinity Healthcare Group A.S.**

| **Harmonised / common standards used** | **Description** |
|---|---|
| EN ISO 13485:2016<br>ISO 13485:2016 | Medical devices. Quality management systems. Requirements for regulatory purposes |
| EN ISO 9001:2015 | Quality management system requirements |
| EN ISO 14971:2019<br>ISO 14971:2019 | Application of Risk management to medical devices. |
| EN ISO 15223-1:2016<br>ISO 15223-1:2016 | Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements |