

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 Skin Barrier, Spray & Wipe			
Legal manufacturer:	Trinity Healthcare Group A.S. Sustekova 3697/49, 85104, Bratislava, Slovakia. Registered in Slovakia No: 56185782			
Single registration number: (SRN)	SK-MF-000045565			
Ref code(s) / Catalogue number(s)	Wipe	TR303	Basic UDI product identifiers	5061066300034
	Spray	TR304		5061066300010
Intended purpose:	Protection of skin from the damage associated with body waste, enzymes and adhesives.			
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:

Mr. L. Pearce

Function:

Chief Executive Officer

On behalf of Trinity Healthcare Group A.S.

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