EU DECLARATION OF CONFORMITY:

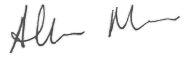
In accordance with Annex IV of EU Medical Device Regulation (MDR); (EU) 2017/745

FOR MEDICAL DEVICE / DEVICE FAMILY (GENERIC DEVICE GROUP):	**STOCARE® PROTECT AND REMOVE**
Legal Manufacturer; Name and Address	**Registered Name:** Rhodes Health Limited **Registered Address:** Newlands House, 60 Chain House Lane, Whitestake, Preston, United Kingdom, PR4 4LG.
Trade Name or Registered Trade Mark	StoCare® Protect Barrier Film Spray StoCare® Protect Barrier Wipes StoCare® Remove Medical Adhesive Remover Spray StoCare® Remove XL Medical Adhesive Remover Spray StoCare® Remove Medical Adhesive Remover Wipes
Legal Manufacturer Single Registration Number (SRN)	UK-MF-000049277
EU Authorised Representative; Name and Address	Apotech consulting France 6bis rue de Verdun 78110 LE VÉSINET
EU Authorised Representative Single Registration Number (SRN)	FR-AR-000039455
Basic UDI-DI for device/device family	06161365STC1JD
Product Codes & Labelling Descriptions	As per ANNEX A
Device Classification; as per Annex VIII of the MDR 2017/745	Class 1 Non-sterile, non-measuring, non-reusable surgical instrument, non-custom made. Rule 4.
Intended Use	**StoCare® Protect** - Provides a barrier layer to protect vulnerable skin from the effects of moisture associated with stoma output and wounds. It also protects skin from the effects of Medical Adhesive Related Skin Injuries (MARSI). The device may also be used to enhance the adhesion of medical incontinence appliances. **StoCare® Remove** - Gently removes medical adhesive from appliances and dressings, such as ostomy pouches, without damaging the skin.
Harmonised Standards, or Common Specifications Applied	As per ANNEX B

Medical Device Regulation 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, as detailed in Article 52 (Point 7).

STATEMENT OF UNDERTAKING:

The undersigned declares that the EU Declaration of Conformity is issued under the sole responsibility of the manufacturer, and that the device(s) listed within are in conformity with EU Medical Device Regulation; (EU) 2017/745

	Name	Title / Function	Location	Date	Signature
Signed by:	Allison Moosa	Director	Whitestake, United Kingdom	16.09.25	
On behalf of	**Registered Name:** Rhodes Health Limited **Registered Address:** Newlands House 60 Chain House Lane, Whitestake, Preston, United Kingdom, PR4 4LG				

ANNEX A: ASSOCIATED MODEL IDENTITIES:

Product Code	Labelling Description
EUSTC100	StoCare® Remove Medical Adhesive Remover Spray 50ml
EUSTC150	StoCare® Protect Barrier Film Spray
EUSTC200	StoCare® Remove Medical Adhesive Remover Wipes
EUSTC250	StoCare® Protect Barrier Wipes
EUSTC300	StoCare® Remove Medical Adhesive Remover Spray 100ml

ANNEX B: HARMONISED STANDARDS, OR COMMON SPECIFICATIONS APPLIED:

Harmonised Standard or Common Specification	Description
EN ISO 14971:2019 ISO 14971:2019	Application of Risk management to medical devices.
EN ISO 13485:2016 ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes
EN ISO 15223-1:2021 ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
EN ISO 20417:2020 ISO 20417:2020	Medical devices — Information to be supplied by the manufacturer
MEDDEV 2.7/1 Rev. 4	Clinical Evaluation : A Guide for Manufacturers and Notified Bodies under Directives 93/42 EEC and 90/385/EEC
ISO 10993-1: 2009	Biological Evaluation of Medical Devices – Evaluation and Testing within a risk management process

ANNEX C: DOCUMENT HISTORY:

Version	Date	Description / Change Detail
1.0	V1	First issue