

1 Issuer's name and address

Name : Bfactory Health Products B.V.
 Trade name / mark : N.A.
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This EU Declaration of Conformity is issued under the sole responsibility of Bfactory Health Products B.V.

2 Object of the declaration

We hereby declare that the CE-marked medical devices, within the product group, conform to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices (Medical Device Regulation, MDR

Product group	EMDN code	Basic UDI-DI	Classification & rule MDR Annex VIII
Barrier Creams	M04040701	08717438ShieldCover7U	Class I (Rule 4)

The intended purpose of the barrier creams Revamil Shield and Cover is to form a mechanical barrier over the skin that protects against moisture-induced damage and shear forces.

The following products/variants fall under the product group listed above:

Models in the device family	Article number	UDI-DI
Cover 60g	11040	8717438010083
Cover 120g	11050	8717438010090
Revamil Shield 60g	10920	8717438011394
Revamil Shield 120g	10930	8717438011387

3 Common Specifications used

The following Common Specification(s) have been used, and conformity is claimed:

Common Specification ID	Description / title of Common Specification
NA	NA

4 Quality Management System

The QMS of Bfactory is certified by DEKRA Certification B.V. to EN ISO 13485:2016:

Certification number	Scope	Expiry date
2166303	Development, Manufacturing and Sales of honey-based medical devices for wound care treatment	1 February 2026

5 Signature

This EU Declaration of Conformity is signed for and on behalf of Bfactory Health Products B.V..

Name	:	Tineke Creemers	Willem Jan Bosma
Function (company)	:	Director and RA Manager	Director and Management Representative
Location and date	:	Rhenen, 25-02-2025	Rhenen, 25/2/2025

Signature


