

RESORBA Medical GmbH

Am Flachmoor 16 · 90475 Nürnberg
Fon +49 (0) 9128/ 91150 · Fax +49 (0) 9128/ 9115 91
informail@resorba.com · www.resorba.com

TFJ-003 rev 1

Addendum to: TFJ-001 rev.1, dated 17 May 2021

EC Declaration of Conformity

Debridement Pad

According to Annex II of the Council Directive 93/42/EEC concerning medical devices we declare by sole responsibility that the medical device:

Name of product: Mepi™ Debripad

Device class

according to Annex IX: Class IIa

Article codes: 300113 Circular Pad 13 cm Diameter

300111 Oval 'Lozenge/Racetrack' 11cm x 18cm

Applied

classification rule: Rule 4

Intended use: Debridement of superficial, chronic and acute wounds and the skin

surrounding the wound.

Manufactured by: RESORBA Medical GmbH

Am Flachmoor 16, 90475 Nürnberg, Germany

conforms with the essential requirements according to Annex I and fulfills Annex II of the Council Directive 93/42/EEC concerning medical devices and all present valid legal regulatory requirements and harmonized standards.

The file

was examined by: Polish Centre for Testing and Certification

469 Puławska Street, 02-844 Warsaw, Poland

Identification number: 1434

EC Certificate No: **1434-MDD-267/2021**

The transfer of appropriate surveillance to Notified Body, British Standards Institution (ID number 2797), The Netherlands B.V., in accordance with Regulation (EU) 2023/607 has concluded (BSI reference AR120 817846).

The changes made comply with the transitional provisions of (EU) 2017/745 Article 120, such that the (EU) Declaration of Conformity (TFJ-001, dated 17 May 2021) has not been invalidated.



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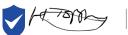
EC Declaration of Conformity

Debridement Pad

This Declaration of Conformity is valid only for batches released successfully in line with RESORBA Medical GmbH's release criteria. RESORBA Medical GmbH declares that these devices manufactured by RESORBA Medical GmbH achieve conformity with the Council Directive 93/42/EEC via Annex II (Full Quality Product Assurance) at the time of release.

Issued in Nürnberg, Germany RESORBA Medical GmbH

Signed by Helen Topping



I approve this document 08-Nov-2024 | 14:29 GMT

08-Nov-2024 | 14:31 GMT

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Helen Topping, Regulatory and Clinical Director

Date