RESORBA Medical GmbH
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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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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
45954AC4F5834D9193F6616921972740

08-Nov-2024 | 14:31 GMT

Helen Topping, Regulatory and Clinical Director Date