

EC Certificate No. 1434-MDD-267/2021 **Full Quality Assurance System** Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies that the quality assurance system in the organization:

RESORBA Medical GmbH

Am. Flachmoor 16 90475 Nürnberg, Germany

for the design, manufacture and final inspection of medical devices, class IIa

Debridement Pad Pad for wound debridement during dressing change

The list of medical devices covered by this certificate is provided in the Annex 1

complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 14.05.2021 to 27.05.2024

The date of issue of the Certificate: 14.05.2021

Issued under the Contract No. MD-103/2020 Application No: 263/2020 Certificate bears the qualified signature. Warsaw, 14/05/2021 Module H2

Anna Małgorzata Małgorzata Wyroba Wyroba /

Elektronicznie podpisany przez Anna Data: 2021.05.17 12:15:15 +02'00'

Vice-President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE No 1434-MDD-267/2021

List of medical devices covered by the certificate:

Debridement Pad – product table

Circular Pad	13 cm Diameter
Oval 'Lozenge/Racetrack'	11cm x 18cm
Oval 'Flat Bottom'	12cm x 18cm

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Issued under the Contract No. MD-103/2020 Application No: 263/2020 Certificate bears the qualified signature. Warsaw, 14/05/2021 Module H2 Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba Data: 2021.05.17 12:14:27 +02'00'

Vice-President





Supplementary information to AR120 817846 *Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3*

Issued to:

RESORBA Medical GmbH Am. Flachmoor 16 90475 Nürnberg, Germany

Date: 14 November 2024

Changes Approved:

Date	Reference Number	Action
14 November 2024	30251377	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of device: Debridement Pad. Original NB Certificate Number: 1434-MDD-267/2021