

EC Declaration of Conformity

Suprasorb® P + PHMB Antimicrobial Foam Dressing (non-adhesive)

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: **Suprasorb® P + PHMB Antimicrobial Foam Dressing (non-adhesive)**
Suprasorb® P + PHMB Antimicrobial Silicone Foam Border Dressing

Device class according to Annex IX: **Class III**

Article codes: See attached **Appendix A**

Applied classification rule: **Rule 13**

Intended use: **Silicone PHMB Foam Wound Dressings are primary wound dressings for use in the management of the moderate to heavily exuding chronic or acute wounds that effectively and rapidly absorb wound exudate and creates the ideal environment for moist wound healing.**

Manufactured by: **RESORBA Medical GmbH**
Am Flachmoor 16, 90475 Nuremberg, Germany

conforms with the essential requirements according 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 design dossier was examined by: **Polish Centre for Testing and Certification**
469 Pulawska Street, 02-844 Warsaw, Poland

Identification number: **1434**

EC Certificate No: **1434-MDD-430/2020**

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.

Nuremberg,
RESORBA Medical GmbH



Rose Guang, VP Regulatory & Clinical Affairs

Date 15 Aug 2023

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Appendix A – Article codes

BRAND NAME	SIZE (cm)	REF CODE
Suprasorb® P + PHMB Antimicrobial Foam Dressing (non-adhesive)	5 x 5	34 540
	7.5 x 7.5	34 541
	10 x 10	34 542
	10 x 20	34 543
	15 x 15	34 544
	20 x 20	34 545
Suprasorb® P + PHMB Antimicrobial Silicone Foam Border Dressing	8 x 8	149 350
	10 x 10	149 351
	10 x 20	149 796
	15 x 15	149 353
	20 x 20	149 354