EU Self Declaration of Conformity
Regulation (EU) 2023/607 for Medical Devices

We, the manufacturer:

Name	Resorba Medical GmbH
Address	Am Flachmoor 16, 90475 Nuremberg Germany
Single Registration Number	DE-MF-000009480

under our sole responsibility, declare that the following devices comply with MDR Article 120 via Regulation (EU) 2023/607 and may be placed on the market or put into service as the following conditions are met:

(a) The devices listed continue to comply with Directive 93/42/EEC.
(b) there have been no significant changes in the design and intended purpose.
(c) The devices listed do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
(d) We will have a quality management system in accordance with Article 10(9). In place before 26 May 2024.
(e) A formal application with a notified body in accordance with Section 4.3, first subparagraph of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device will be made.
(f) A written agreement in accordance with Section 4.3, second subparagraph of Annex VII, signed by the Notified Body will be in place no later than 26 September 2024.

Product Name	Product Code	Size	BASIC UDI-DI
PARASORB® Cone	DK1010	PARASORB® Cone (Ø 1.2cm, H: 1.6 cm)	50599812090102UQ

Device Family	PARASORB® Cone
Intended Purpose:	Sterile haemostatic collagen cone
Classification Rule Under Annex VIII:	Class III
Certification	1434-MDD-192/2021 and 1434-MDD-193/2021
Common Specification:	N/A

The devices listed above are in conformity with the requirements of Article 120 via Regulation (EU) 2023/607 and we confirm a written agreement in accordance with Section 4.3 of Regulation (EU) 2017/745 is already implemented.

EU Self Declaration of Conformity Regulation (EU) 2023/607 for Medical Devices Form	
Group Form	**Revision**
GRP-FRM-0069	2

The following signatory is provided for and on behalf of RESORBA Medical GmbH.

Name	Helen Topping	**Date** 19-Dec-2023 | 14:44 GMT
Position	Regulatory and Clinical Director – Biosurgicals and Sutures	DocuSigned by Helen Topping I approve this document 19 Dec 2023 | 14:43 GMT 45954AC4F5834D9193F6616921972740
Place of issuance	Resorba Medical GmbH, Nuremberg, Germany	