

EU Declaration of Conformity
Council Directive 93/42/EEC on medical devices

We, the manufacturer:

Name	RESORBA Medical GmbH
Address	Am Flachmoor 16 90475 Nürnberg Germany
Single registration number	N/A*

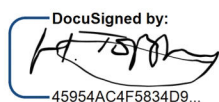
under our sole responsibility, certify that the products described below are in conformance with the applicable provisions of the Council Directive 93/42/EEC concerning medical devices:

Device family:	PARASORB [®] Cone GENTA <i>Alternative trade names¹: RESORBA[®] CONE GENTA, DENTAL CONE G[™]</i>
Intended purpose:	Sterile haemostatic collagen cone with gentamicin.
Classification rule under Annex VIII:	Class III under Rule 13 & 17
DE Certification:	1434-MDD-263/2020
EC Certification:	1434-MDD-264/2020

Product name	Product code	Basic UDI-DI
PARASORB [®] Cone GENTA ((Ø 1.2 cm, H: 1.6 cm)	MK10	N/A*
PARASORB [®] Cone GENTA (Ø 1.2 cm, H: 1.6 cm)	MK11	

The devices listed above have undergone conformity assessment by Polish Centre for Testing and Certification S.A. (ID number 1434) in accordance with the requirements of Annex II.

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

DocuSigned by:

45954AC4F5834D9...

3/12/2021 | 13:08 GMT

Name Helen Topping
Position Senior RA Manager
Place of issuance Resorba Medical GmbH

Date

¹ Alternative trade names are included in the current product certification; however, they are not yet being manufactured and therefore have no product code.

* N/A – not applicable for conformity with the EU Council Directive 93/42/EEC on medical devices (MDD)