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HARTMANN
Going further for health

EC-Declaration of Conformity for Medical Device Class IIb

Heidenheim, 2019-05-06

We herewith declare,

Object of the declaration: **Zetuvit® Plus Silicone Border / RespoSorb® Silicone Border**

which is first placed on the market by PAUL HARTMANN AG, meet the applicable provisions, especially the Essential Requierements of the following EC-regulation:

- **Council Directive 93/42/EEC for medical devices**

The conformity assessment procedure is under the supervision of the Notified Body:
TÜV SÜD Product Service GmbH, DE-80339 München, Ridlerstr. 65, Identification No. 0123.

Medical Device: Class IIb acc. to rule 4(2)

(acc. to Annex IX of the directive)

UMDNS: 15216

PAUL HARTMANN AG

i.V.

Jens Hahn
Senior Manager Regulatory Affairs

ppa.

Stefan Fischer
Senior Vice President Regulatory Affairs

This document is valid until: 2019-09-30.

IILN 040 9500 00000 0

Vorstand/ Management Board: Britta Fünfstück (Vorstandsvorsitzende/ CEO). Dr. Raymund Heinen. Michel Kuehn. Stephan Schulz.
Aufsichtsratsvorsitzender/ Chairman of the Supervisory Board: Fritz-Jürgen Heckmann

Sitz Heidenheim
Amtsgericht Ulm HRB 661090

Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB 661090