

PAUL HARTMANN AG
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Going further
for health

EC-Declaration of Conformity for Medical Device Class IIa

Heidenheim, 2018-0627

We herewith declare,

Object of the declaration: Veroval Duo Control

which is first placed on the market by PAUL HARTMANN AG, meet the applicable provisions, especially the essential requirements of the following EC-regulation(s):

- **Council Directive 93/42/EEC for medical devices**
- **Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment**

For Medical Device Regulation:

The required conformity assessment procedure according to Annex II excluding (4) has been performed and the technical documentation is kept available.

This EC-Declaration of Conformity is issued under the sole responsibility of the PAUL HARTMANN AG.

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 IIa acc. to rule 10 (3.)
(acc. to Annex IX of the directive)

UMDNS: 16-173

For 2011/65/EU (recast):

The Object of the declaration are in conformity with the relevant harmonized standards used or references to the technical specifications in relation to which conformity is declared:

- EN 50581

PAUL HARTMANN AG

ppa.

Jörg Richter
Head of Business Division
Personal Health Care

ppa.

Stefan Fischer
Head of Regulatory Affairs

This document is valid until: 2018-09-30

IILN 040 9500 00000 0

Vorstand/ Management Board: Andreas Joehle
(Vorstandsvorsitzender/ 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