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HARTMANN

Going further
for health

EC-Declaration of Conformity for Medical Device Class I sterile

Heidenheim, 2019-02-12

We herewith declare,

Object of the declaration: **Stérilux Compresses ophtalmiques (Stérilux eye pads)**

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

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

The required conformity assessment procedure according to Annex VII in connection with Annex V 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 1 acc. to rule 4 (acc. to Annex IX of the directive)

UMDNS: 11-661

PAUL HARTMANN AG
ppa.

Dr. Laurent Roche
Global Product Marketing Wound Management

i.V.

Dr. Michaela Akermann
Head of Regulatory Affairs Submissions

This document is valid until: 2019-09-30