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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity Class Is

Heidenheim, 2023-03-14

We herewith declare under our sole responsibility that the Class I sterile medical devices listed below, first placed on the market by PAUL HARTMANN AG, Single Registration Number of Manufacturer DE-MF-000005861, satisfy the applicable provisions, in particular, the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (7) and Annex XI part A with respect to sterility have been performed and the Technical Documentation is kept available.

The sterilization processes are under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123. Certificate No.: G21 011858 0069.

Device Group	Z129080 - Various instruments for functional exploration and therapeutic interventions - hardware accessories		
Device Properties	MDS 1005.1 Ethylene Oxide Sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
MediSet Forceps with thin jaws (sterile)	3793	5	40495003793LR

PAUL HARTMANN AG
ppa.

Martin Walther

Senior Vice President Risk Prevention

Valid until: 2024-06-30

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs