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HARTMANN
Helps. Cares. Protects.

UK Declaration of Conformity for Medical Devices in Class I unsterile

Heidenheim, 2024-07-16

We herewith declare under our sole responsibility of the manufacturer that the Class I medical device 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 Essential Requirements, of UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) which were amended by the Medical Devices (EU Exit) Regulations 2019 and the Medical Devices (EU Exit) Regulations 2020.

The conformity assessment procedures according to Annex VII have been performed and the Technical Documentation is kept available.

UK Representative

PAUL HARTMANN LTD,

Unit P2, Parklands, Heywood Distribution Park, Pilsworth Road

Heywood, Lancs., OL10 2TT

Intended Purpose	Non-active, non-implantable devices for incontinence care, worn on the body		
Product Name	**Product Group Number**	**Classification Rule** (according to Annex IX of Directive 93/42)	**Basic UDI-DI**
MoliCare Pad	3817	1	40495003817LE

PAUL HARTMANN AG

ppa.

Stefan Grote
Member of the Management Board

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until: 2025-06-30