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UK Declaration of Conformity for Medical Devices in Class I unsterile

Heidenheim, 2023-11-13

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-00005861, 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 Pants	3155	1	40495003155KK

PAUL HARTMANN AG

Stefan Grote

Member of the Management Board

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2024-06-30

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin,

Stefan Grote, Stefan Müller

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