EC DECLARATION OF CONFORMITY

Legal Manufacturer:

Name:	Novamed Europe Ltd
Address:	Unit 4, Coopers Place Combe Lane Wormley, Godalming Surrey GU8 5SZ, England
Single Registration Number	UK-MK-000040737
Basic UDI-DI and Product Description	506052477UP-X25MF – Novamed Underpads 506052477ALL-IN-ONEYJ- Novamed All-in-one / Diaper 506052477PANTS9R – Novamed Pull up Pants 506052477BIL-10UV – Novamed Bamboo Light Pads
Product / Trade Name(s) and/or product code(s) REF	Novamed Disposable Hygiene Products listed in Appendix I
Intended Purpose	Diapers and other disposable hygiene products to absorb urine and faeces for incontinent patients
Risk Classification	Class I non sterile without measuring function, Rule 1 as per Annex VIII of Regulation (EU) 2017/745
Conformity Assessment Procedure	The Technical Documentation is in compliance with Annex II and Annex III of Regulation (EU) 2017/745

Other Information (if applicable):

Applied Harmonized Standards and Technical Specification	ISO 13485:2016 ISO 11948-1 Forecasts absorbency performance in disposable incontinence pads ISO 14971:2020 – Medical Products – Risk Management ISO 1041:2012 – Information supplied by the producer together with the medical device ISO 908:2010 – Graphical symbols used or medical product labelling
Notified Body name and identification No. and description of the conformity assessment procedure performed	Not relevant for Class I products
EU Representative	MDSS Gmbh Schiffgraben 41 30175 Hannover Germany SRN- DE-AR000005430

The aforementioned mentioned medical devices in “UDI-DI and Product Description” are in conformity with the Regulation (EU) 2017/745 and, if applicable, with any other relevant Union Legislation that provides for the issuing of an EU declaration of conformity.

The technical documentation as per Annex II and III of Regulation (EU) 2017/745 is kept by the Manufacturer for a period of not less than 10 years. EU Declaration of conformity is used under the sole responsibility of the manufacturer.

Signature: Prableen

Name: Mrs. Prableen Sethi Kohli

Job Description: Managing Director

Company: Novamed Europe Ltd

Date and Place: 20-05-2024, Surrey

Product Technical File: TD:0 Version 1

Novamed (Europe) Limited

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