EC/UK Declaration of Conformity

Manufacturers Name:	[UI MEDICAL, LLC]
Manufacturers Address: **Mailing Address:**	[1670 Park Avenue. Redlands, California 92373 USA.] [555 E. Ocean Blvd., Suite 400. Long Beach, California 90802 USA.]
UK Responsible Person:	[QCS International Ltd.]
UK Responsible Person Address:	[Suite 9, Cumbernauld Business Park, Cumbernauld, G67 3JZ, UK]
Basic UDI-DI:	[GS1 08618590004]
Name of the Device (s):	[QuickChange Incontinence Wrap]
Product code:	[UIM 1005, UIM 1010, UIM 1025, UIM 2025, UIM 2050]
GMDN:	[35817]
Classification:	[CLASS I, Non-Sterile, Non-Measuring]
Conformity assessment route:	[UI MEDICAL, LLC] uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745 and UK Medical Device Regulations 2002 (SI 2002 no. 618, as amended) : Class [I Non-Sterile, Non-Measuring]: EC conformity declaration according to Annex VIII of 2017/745 and Annex VII of 93/42/EC as required by UK Medical Device Regulations 2002 (SI 2002 no. 618, as amended).

This declaration of conformity is issued under the sole responsibility of [UI MEDICAL, LLC]. We hereby declare that he medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 and UK Medical Device Regulations 2002 (SI 2002 no. 618, as amended) for medical devices. All supporting documentation is retained at the premises of the manufacturer and with the UK responsible person.

Signature:

X .....

NICOLAS SOICHET, President

Place and date (dd.mm.yyyy) of issue:

X 28/01/2021 .....