UI MEDICAL
555 E. OCEAN BOULEVARD STE 400
LONG BEACH, CA 90802
(562) 453-1515 www.quickchange.com

EC DECLARATION OF CONFORMITY

With regard to Article 19 and Annex IV of Regulation (EU) 2017/745 for Medical Devices

Manufacturer Name	:	**UI MEDICAL LLC**
Registered Trade Name / Registered Trademark	:	Not Applicable
Legal Manufacturer Address	:	1670 West Park Avenue, Redlands, California 92373, United States
SRN (Single Registration Number)	:	Not Available
Authorized Representative Name	:	**EUROPECERT**
Authorized Representative Address	:	Alsstr. 97, 41063 Mönchengladbach, Germany support@europecert.eu
Basic UDI-DI	:	GS1 08618590004
Name of the Product	:	**Incontinence Pants Liner**
Trade Name	:	**QuickChange Incontinence Wrap**
Variants/Models	:	Not Applicable
Catalogue Number	:	Not Applicable
Photograph of the Product	:	
Intended Purpose	:	The Incontinence pants liner is a protective garment for incontinence that consists of absorbent padding and a fluid barrier that is intended to protect an incontinent patient's garments and/or skin from the patient's urine .

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Risk Classification of the Device with Justification	:	**CLASSIFICATION:** The Incontinence pants liner is classified as Class I which comes under Rule 4 of Annex VIII of Regulation (EU) 2017/745. **JUSTIFICATION:** As per Annex VIII of EU MDR 2017/745, Chapter III, Invasive device, Classification Rules, Rule 4: All non-invasive devices which come into contact with injured skin or mucous membrane are classified as class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates.
References to any CS (if used)	:	Not Applicable

We hereby under our sole responsibility declare that the product to which this declaration relates, is in conformity with the relevant provisions of standards and other normative document(s) and fulfills the general safety and performance requirements of Annex I of Regulation (EU) 2017/745 for conformity assessment through Technical Documentation as per Annexures II and III of EU Medical Device Regulation 2017/745.

The declaration is based on

a) **Harmonized Standards:** EN ISO 13485:2016, EN ISO 10993-1:2020, , EN ISO 20417:2021, EN ISO 14971:2019, EN ISO 15223-1:2021.

b) **Non-Harmonized Standards**: ISO 11948-1:1996

c) **Technical File No. with issue date: UM**L-TF-01,Revision No. R00; 07-02-2022

Name : **J. Baum Harris**

Designation : **Managing Member**

Signature : 

Date : 07-02-2022

Place : **California, United States**