Product: MOWOOT II

Legal Manufacturer: usMIMA, S.L.

SRN: ES-MF-000000232

Address: Avinguda Cornellà 140, 6A, 08950 Esplugues de Llobregat, Barcelona, Spain.

Telephone: +34 935 106 653 / +34 664 361 255

Statement: Hereby declare, as the sole legal manufacturer of MOWOOT II medical devices, that the present EU Declaration of Conformity is issued under our sole responsibility.

This EU declaration of conformity covers "**MOWOOT II Medical device"** as specified in the product list belonging to this declaration and is valid for all products concerned bearing the CE marking.

The MOWOOT II device conforms with the relevant UK Statutory Instruments and their amendments: UK MDR 2002 (Medical Device Regulations (2002) (SI 2002 no618). Conformity assessment route: Part II of the UK Medical Device Regulations.

Basic UDI-DI: The following list identifies the products by name, model number, UDI-DI, serial number and/or other time related information:

Product Name	Basic UDI-DI	REF	UDI-DI (GTIN)
Pneumatic Console MOWOOT II	8437016001MOWOOTII7E	MW2-D01	8437016001073
Exoperistaltic Belt Size S	8437016001MOWOOTII7E	MW2-B01	8437016001066
Exoperistaltic Belt Size M	8437016001MOWOOTII7E	MW2-B02	8437016001134
Exoperistaltic Belt Size L	8437016001MOWOOTII7E	MW2-B03	8437016001141
Exoperistaltic Belt Size XL	8437016001MOWOOTII7E	MW2-B04	8437016001158
Power supply MII	8437016001MOWOOTII7E	MW2-PS1	8437016001080
Block Connector MII	8437016001MOWOOTII7E	MW2-BC1	8437016001097

Pack MOWOOT II	8437016001MOWOOTII7E	MW2-P01	8437016001059
Desktop Packaging MII	8437016001MOWOOTII7E	MW2-PD1	8437016001202
Belt Packaging MII	8437016001MOWOOTII7E	MW2-PB1	8437016001219

Intended use: Instrumental treatment and management of chronic constipation, intended for use at home & for inpatient use (e.g., hospitals, nursing homes and retirement homes) by patients (paediatric and adult) or healthcare professionals.

Risk Class: According to:

- MDR (EU) 2017/745, Annex VIII Rule 9 (active devices).
- Part II of MDR 2002, set out in Annex IX of MDD 93/42/EEC, Rule 9.

to the classification of medical devices, and especially due to its design, manner of use, and action, **MOWOOT II** is classified as **class IIa** because is an active device which exchange energy without any hazard.

Regulation: MOWOOT II medical devices meet the provisions of MDR (EU) 2017/745, which apply to them, as well as the following Standards and Directives:

· UNE EN ISO 13485	· UNE EN ISO 14971	· EN 1041
· UNE EN ISO 15223-1	· UNE EN ISO 10993-1	·UNE EN ISO 10993-18
· IEC 6060-1-1	· IEC 6060-1-1-2	· IEC 6060-1-1-6
· IEC 6060-1-1-8	· IEC 6060-1-1-11	· UNE EN 62304
· UNE EN 62366	· UNE EN ISO 14155	· Directive 2012/19/EU
· Directive 2011/65/EU	· Directive 2006/42 EC	· Regulation 2016/679

Notified Body: BSI Group – Netherlands (2797)

Approved Body: BSI Assurance UK Ltd (0086)

UK Responsible Person: Emergo Consulting (UK) Limited – c/o Cr360 – UL International, Compass House, Vision Park Histon, Cambridge CB24 9BZ, United Kingdome

Conformity Assessment Procedure:

- MDR (EU) 2017/745, Annex IV and Annex IX
- Part II of the UK Medical Device Regulations

BSI's Certificates – MDR 740877 & UKCA 771101, Valid until: 22/11/2027

Quality System	BSI Assurance UK Ltd (0086)
Manufacturing:	ISO 13485:2016, MD Certificate nº: 649373, Valid until: 22/08/2025

Location & Date:	Barcelona, 10/07/2023	**Validity Period:**	5 years

Name	Position	Signature & Date
Markus Wilhelms	C.E.O – usMIMA, S.L.	Markus Wilhelms Digitally signed by Markus Wilhelms Date: 2023.07.12 17:24:45 +02'00'