Biemme Group S.r.l.
Via Ugo la Malfa, 5
42048 Rubiera (RE) – Italia
Tel. +39 0522 1493390
www.biemmegroupsrl.it

CE

Declaration of conformity EU

(Anex IV Reg.EU.DM 2017/745)

Manufacturer seated in EU	**Biemme Group S.r.l.** Via Ugo la Malfa, 5 42048 Rubiera (RE) – Italy Tel. +39 0522 1493390 www.biemmegroupsrl.it
SRN	**IT-MF-000031381**
Product name (may include accessories)	**Ultralight manual wheelchair**
Risk classification	**Class I**
Model	**FELIX**
Basic UDI-DI	**805050779001AD**

Applicable standards	**EN ISO 14971:2019/A11:2021**	Medical devices - Application of risk management to medical devices.
	EN 12183:2022	Manual wheelchairs - General requirements and test methods.
	EN ISO 20417:2021	Medical devices - Information provided by the manufacturer.
	EN 15223-1:2021	Medical devices - Symbols to be used in medical device labels, labelling and information provided – Part.1 – General requirements.
	EN 62366-1: 2015/AC:2015/A1:2020	Medical devices – Part.1 - Application of usability engineering to medical devices.

This product is classified as Class I, as per Rule 1 of Anex VIII of the **MDR 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices, complies with general safety and performance requirements and is also subject to the procedure set out in Annexes II and III of the same Medical Devices Regulation.

We, **Biemme Group S.r.l.,** manufacturer of the medical device identified as **Ultralight manual wheelchair FELIX**, hereby declare under our sole responsibility that the product is in conformity with requirements of above-mentioned regulation.

Rubiera, 16/12/2023

Revision No.	Date	Print name	Function
00	02/01/2020	Ivano Cerri	Technical Director
01	01/10/2021	Ivano Cerri	Technical Director
02	01/12/2022	Ivano Cerri	Technical Director
03	16/12/2023	Ivano Cerri	Technical Director
Signature	Ivano Cerri		