J58 Holding B.V.
Europalaan 188, 7543 DK Enschede, The Netherlands
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EU DECLARATION OF CONFORMITY

As manufacturer of the Ezer standing wheelchair, the company

Manufacturer name and address:	J58 Holding B.V. Europalaan 188, 7543 DK Enschede, The Netherlands
SRN (Single Registration Number):	NL-MF-000046315
Authorized Representative name and address (if applicable):	NA

hereby declares under our sole responsibility that the device listed in the attached Annex complies with the provisions of the REGULATION (EU) 2017/745.

The device Ezer standing wheelchair (Model 002. Basic UDI GTIN (UDI-ID): 7649994843021) is Class 1 following Rule 1 of Annex VIII of REGULATION (EU) 2017/745.

The following conformity assessment procedure has been performed (in according to MDR Art 52).

The following Standards have been used and in relation to which conformity is declared:

List of Applicable Standards	
Reference	**Title**
EN ISO 13845:2016	*Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)*
ISO 15223-1:2021	*Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*
EN ISO 14971:2019	*Medical devices — Application of risk management to medical devices*
EN ISO 20417:2021	*Information supplied by the manufacturer of medical devices*
EN ISO 10993-1:2018	*Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
EN 12182:2012	*Assistive products for persons with disability- General requirements and test methods*
EN 12183:2022	*Manual wheelchairs - Requirements and test methods*

We hereby also declare under our sole responsibility that the device listed in the annex complies with the provisions of Regulation (EU) 2017/745

The present declaration is in conformity with Regulation (EU) 2017/745 and with the standards listed in the table- list of applicable standards

Dr. Rivelino Montenegro, Regulatory Affairs

Enschede (The Netherlands) 24th Nov 2025

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Reference to other documents:

- This Declaration of Conformity is supported by the complete technical documentation compiled in accordance with Annex II and Annex III of Regulation (EU) 2017/745, which includes:

- Risk management file as per EN ISO 14971:2019
- Instructions for Use (IFU)
- Manufacturing and quality control procedures
- Installation, servicing, storage, handling, and packaging instructions

- The device is accompanied by Instructions for Use that comply with Annex I, Chapter III of Regulation (EU) 2017/745 and EN ISO 20417:2021. The IFU provides comprehensive information on the intended purpose, installation, operation, maintenance, warnings, and precautions.
- Risk management has been applied throughout the product lifecycle in accordance with EN ISO 14971:2019. A full risk management file is available in the technical documentation and includes risk identification, analysis, evaluation, control, and monitoring.
- Servicing and installation procedures are documented and maintained in the technical file. These ensure continued performance, safety, and compliance throughout the product's lifetime.

Annex - List of Devices Covered by the Declaration of Conformity

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN/EMDN code
1	Wheelchair	Ezer (Model 002)	The mechanical standing wheelchair (Ezer) is a non-sterile, Class 1 device. It enhances the life of disabled persons by giving them a means to stand	The device is intended for medical purposes to provide seating and standing mobility to people restricted in a sitting position	Class 1	Rule 1	GTIN (UDI-ID): 7649994843021	41622/ Y122106 & Y122609 (Rear/Front Self Propelled Wheelchairs)