EU DECLARATION OF CONFORMITY

According to MDR 2017/745 Article 19 and Annex IV

LOJER® For easy care

Document ID	0008
Manufacturer information	Lojer Oy Putajantie 42, P.O.Box 54 FI-38210 Sastamala, Finland
Single Registration Number (SRN)	FI-MF-000001639
Product	Modux nursing beds (models Modux 480, Modux 490)
Basic UDI-DI	643002193NB0001LX
Product class According to MDR Annex VIII	Class I, Rule 13
Laws and regulations that the product is in conformity with	MDR 2017/745 REACH regulation (EC 1907/2006) RoHS Directive (2011/65/EU) Directive 2014/30/EU
Harmonized standards applied in design and manufacturing of the product	EN 60601-1:2006 + A1:2013 EN 60601-1-2:2015 EN 60601-1-6:2010 EN 60601-1-11:2010 EN 60601-2-52:2010 EN ISO 14971:2012 EN ISO 13485:2016 EN ISO 15223-1:2016

Lojer Oy as the manufacturer declares that this product is in conformity with Medical Devices Regulation 2017/745 and with other laws and regulations listed on the table above. This declaration of conformity is issued under the sole responsibility of the manufacturer.
The product is marked with CE-marking.

Signature

Mika Kuusela

On behalf of Lojer Oy
Mika Kuusela,
R&D Manager

LOJER OY * LOJER For easy care * SASTAMALA • FINLAND

Date (DD-MM-YYYY)

21.05.2021

Place: Sastamala Finland