CE

EU DECLARATION OF CONFORMITY

OBJECT:	T35IDRO IPERESTENSORE IDRO IDRO HYPEREXTENSION	ref: T35IDRO/L UDI-DI 8053670824607 T35IDRO/M UDI-DI 8053670824591 T35IDRO/S UDI-DI 8053670824614 T35IDRO/XL UDI-DI 8053670824621

The undersigned Tecnoway srl with administrative headquarters in Montefeltro Street n. 45 Vallefoglia –PU- Italy

Declares

Under its own responsibility that the device complies with all applicable provisions of EU Regulation 2017/745 on medical devices.

For this purpose Tecnoway srl declares that the device in question:

- *It's a class I medical device according to rule 1, annex VIII of the EU Regulation 2017/745*
- *Meets the applicable general safety and performance requirements as set out in the annex I of the EU Regulation 2017/745*
- *Complies with the standards of the following harmonized rules/common specifications:*

RULE	RULE DATE
UNI EN ISO 9001:2015	22/09/2015
UNI EN ISO 13485:2016	25/10/2016
UNI EN ISO 14971:2019	10/12/2019
ISO/TR 24971:2020	16/06/2020

Vallefoglia 06/12/2022

Tecnoway srl
il legale rappresentante

TECNOWAY
ENGINEERING AND MANUFACTURING OF MEDICAL DEVICES

TECNOWAY srl
via Montefeltro n. 45 - 61022 Vallefoglia (PU)
Tel. 0721 496175
info@tecnoway.it - www.tecnoway.it