DECLARATION OF CONFORMITY

We,

GymnaUniphy N.V.

SRN BE-MF-000001786

Pasweg 6a, 3740 Bilzen, Belgium

head office

declare, entirely on our own responsibility, that the product(s) to which this declaration relate(s), meet(s) the provisions of the Medical Device Regulation (MDR) 2017/745 and the general safety and performance requirements of Annex I of this regulation.

Conformity assessment is according to Annex IX of the MDR. The Quality System certification is based on harmonized standard EN ISO 13485:2016, issued together with the EC Certificate *2257802CE01* by DEKRA Certification B.V., the Netherlands, Notified Body number 0344.

gymna Elexeo series

Official label	***Administrative use***
Elexeo Electrotherapy control	***Elexeo Electrotherapy (ET) control unit***
Elexeo Ultrasound control	***Elexeo Ultrasound (US) control unit***
Elexeo Electrotherapy module	***Elexeo Electrotherapy (ET) module***
Elexeo Ultrasound module	***Elexeo Ultrasound (US) module***
Elexeo Vaco module	***Elexeo Vaco module***
Elexeo Battery pack	***Elexeo Battery module***

and all accessories

Device for multiple non-invasive electrophysical modalities

Basic UDI-DI: <5425022610106S3>

Serial Numbers:

Elexeo ET control ≥ YT0700100
Elexeo US control ≥ YT0800100
Elexeo ET module ≥ YT0900100
Elexeo US module ≥ YT1000100
Elexeo Vaco module ≥ YT1100100
Elexeo Battery module ≥ YT1200100

Classification according to rule 9 of Annex VIII of the MDR.
Class IIa

CE 0344

Bilzen, 2025-05-08

Bart de Bresser,
Chief Executive Officer