DECLARATION OF CONFORMITY

GN MED s.r.l.

with registered seat in Viale della Lirica, 11 RAVENNA
and operating seat in Via Bentivoglio, 7/9 IMOLA (BO)

declares under its full responsibility that the product

LASER DEVICE FOR PHYSIOTHERAPY

Identified by the name:

LASER FT-245

Serial No.: LVXXXXX

is in compliance with the essential requirements of the medical devices 93/42/EEC Directive as amended by the 2007/47/EC Directive and subsequent integrations, received in Italy with the D.Lgs (legislative decree) 46/97, modified by the D.Lgs 37/10 and subsequent integrations.
The product is classified as class IIb for rule 9 according to the 93/42/EEC Directive and has been certified with Reg. Number MED 27021 following the certification procedure required by the Annex II, without point 4, of the same Directive by Kiwa Cermet Italy, S.p.A., located in via Cadriano 23 – Granarolo Emilia (BO) identified by the number 0476.

Additionally, GN MED declares that the device is compliant with the following harmonized standards:

EN 60601-1 :2006/A11 :2011/A1 :2013 Medical electrical equipment. Part 1: General requirements for basic safety"

EN 60601-2-22: 2013 Medical electrical equipment. Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment"

EN 60601-1-2:2015 "General requirements for safety - Collateral standard: Electromagnetic compatibility. Requirements and tests".

The Managing Director
Coratella Nicola

Imola 24 / 03 / 2020

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