



Milan, 21 November 2023
C/0664/23/GL/mab

To: DOMINO S.R.L.
VIA VITTORIO VENETO 52
31013 CODOGNE', TV

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificate n° **MED 23006 rev 20 – Directive 93/42/EEC (MDD)**

This letter confirms that, Bureau Veritas Italia SpA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1370 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement (number 510510 - rev 4) in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

DOMINO S.R.L.
VIA VITTORIO VENETO 52
31013 CODOGNE', TV
ITALY

Tabella n.1

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	Device name under MDD corresponding to the device under MDR application	MDD/AIMDD Certificate Reference(s) of the devices under MDR application
ACTIVA 700 AMI MED CYCLING PRO ELITE ELITE 150 GENESY 300 PRO GENESY 600 GENESY 1500 MY MAX MY REHAB PREMIUM 400 PROSTIM 4 PS4 RUNNER PRO SOCCER PRO SWING PRO TENS 3 TENS 6 TENS 15 TENS MED S84 THE CHAMPION THE CHAMPION PRO XT	Ila	ACTIVA 700 AMI MED CYCLING PRO ELITE ELITE 150 GENESY 300 PRO GENESY 600 GENESY 1500 MY MAX MY REHAB PREMIUM 400 PROSTIM 4 PS4 RUNNER PRO SOCCER PRO SWING PRO TENS 3 TENS 6 TENS 15 TENS MED S84 THE CHAMPION THE CHAMPION PRO XT	Certificate n. MED 23006 – rev. 20 issued on 2021/05/18 by the ON 0476



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TRIATHLON PRO AMI LIFE AMI PRO GENESY 3000 GENESY 4000 XT		TRIATHLON PRO AMI LIFE AMI PRO GENESY 3000 GENESY 4000 XT	
DIACARE 7000 DIACARE 7000 RE TECAR BEAUTY 7000 MED TECAR BEAUTY 7000 MED RE DIACARE 7500 MAXIMA RIGENA DIACARE 6500	Ila	DIACARE 7000 DIACARE 7000 RE TECAR BEAUTY 7000 MED TECAR BEAUTY 7000 MED RE DIACARE 7500 MAXIMA RIGENA DIACARE 6500	Certificate n. MED 23006 – rev. 20 issued on 2021/05/18 by the ON 0476
DIACARE 5000 DIACARE 5000 RE TECAR BEAUTY 6000 MED TECAR BEAUTY 6000 MED RE	Ila	DIACARE 5000 DIACARE 5000 RE TECAR BEAUTY 6000 MED TECAR BEAUTY 6000 MED RE	Certificate n. MED 23006 – rev. 20 issued on 2021/05/18 by the ON 0476
PHYSIOLASER 6.0 PRO PHYSIOLASER 12.0 PRO PODCARE 2.0 PRO PODCARE 6.0 PRO PODCARE 12.0 PRO PHYSIOLASER 500 PHYSIOLASER 1000 PODCARE 2.0 PODCARE 6.0 PHYSIOLASER 2.0 PHYSIOLASER 6.0 PHYSIOLASER 12.0 HANDPIECE 1064 HANDPIECE BLACK 808 HANDPIECE GREEN 808 HANDPIECE HP 808 HANDPIECE HP 980 HANDPIECE MP 808 HANDPIECE MP 980 HANDPIECE WHITE 808	Ilb	PHYSIOLASER 6.0 PRO PHYSIOLASER 12.0 PRO PODCARE 2.0 PRO PODCARE 6.0 PRO PODCARE 12.0 PRO PHYSIOLASER 500 PHYSIOLASER 1000 PODCARE 2.0 PODCARE 6.0 PHYSIOLASER 2.0 PHYSIOLASER 6.0 PHYSIOLASER 12.0 HANDPIECE 1064 HANDPIECE BLACK 808 HANDPIECE GREEN 808 HANDPIECE HP 808 HANDPIECE HP 980 HANDPIECE MP 808 HANDPIECE MP 980 HANDPIECE WHITE 808	Certificate n. MED 23006 – rev. 20 issued on 2021/05/18 by the ON 0476
MAGNETO PRO 100 MAGNUM 3000 PRO (Solenoidi Flessibili) MAGNUM 3000 PRO (Solenoidi Soft) MAGNUM 3000 PRO (Pocket Pro) MAGNUM 3000 PRO MAGNUM 3500 PRO MAGNUM XL PRO solenoidi flessibili MAGNUM XL PRO solenoidi soft MAGNUM XL PRO solenoidi pocket pro MAGNUM XL solenoide flessibile MAGNUM XL solenoide soft MAGNUM L solenoide flessibile MAGNUM 2 PRO DRIVE MAGNUM 2500 solenoidi flessibili	Ila	MAGNETO PRO 100 MAGNUM 3000 PRO (Solenoidi Flessibili) MAGNUM 3000 PRO (Solenoidi Soft) MAGNUM 3000 PRO (Pocket Pro) MAGNUM 3000 PRO MAGNUM 3500 PRO MAGNUM XL PRO solenoidi flessibili MAGNUM XL PRO solenoidi soft MAGNUM XL PRO solenoidi pocket pro MAGNUM XL solenoide flessibile MAGNUM XL solenoide soft MAGNUM L solenoide flessibile MAGNUM 2 PRO DRIVE MAGNUM 2500 solenoidi flessibili	Certificate n. MED 23006 – rev. 20 issued on 2021/05/18 by the ON 0476



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MAGNUM 2500 solenoidi soft MAGNUM 2500 solenoidi pocket pro MAGNETO CEMP ELITE		MAGNUM 2500 solenoidi soft MAGNUM 2500 solenoidi pocket pro MAGNETO CEMP ELITE	
MEDISOUND 3000 WELLSOUND PLUS MEDISOUND 1000	Ila	MEDISOUND 3000 WELLSOUND PLUS MEDISOUND 1000	Certificate n. MED 23006 – rev. 20 issued on 2021/05/18 by the ON 0476
KINEO LEG PRESS KINEO MULTISTATION KINEO PULLEY SQUAT KINEO CURL KINEO LEG EXTENSION KINEO LEG PRO KINEO PULLEY	Ila	KINEO LEG PRESS KINEO MULTISTATION KINEO PULLEY SQUAT KINEO CURL KINEO LEG EXTENSION KINEO LEG PRO KINEO PULLEY	Certificate n. MED 23006 – rev. 20 issued on 2021/05/18 by the ON 0476
TENSMED S82 DUO TENS ELITE S2 GENESY S2 NO MIGRAINE PELVIC PRO PS2 PROSTIM 2 TENS PRO NO PAIN	Ila	TENSMED S82 DUO TENS ELITE S2 GENESY S2 NO MIGRAINE PELVIC PRO PS2 PROSTIM 2 TENS PRO NO PAIN	Certificate n. MED 23006 – rev. 20 issued on 2021/05/18 by the ON 0476

In accordance with EU Regulation 2023/607 of the European Parliament of the Council of 15 March 2023, Bureau Veritas Italia hereby confirms that:

- The above-mentioned agreement (n. 510510 - rev 4) was signed within 2024/09/26;
- Bureau Veritas Italia Spa is not responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical devices for which an agreement has been signed for certification according to EU Regulation 2017/745 (MDR) as shown in table n.1.

As required by EU Regulation 2023/607, the validity of the MDD certificate n. MED 23006 – rev. 20 is extended until 2028/12/31, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.

Confirmation Letter Revision History

Date	Revision	Action
2023/06/07	0	First issuing
2023/11/21	1	Re-issuing, a model was added



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GIORGIO LANZAFAME
Bureau Veritas Italia S.p.A.
Certification Division
LOCAL TECHNICAL
MANAGER