




DECLARATION OF CONFORMITY

Manufacturer	İNCELER MEDİKAL SAĞLIK HİZMETLERİ SAN. VE TİC. LTD. STI. İvedik Organize Sanayi Bölgesi Mahallesi 1472 Cadde No:120 Yenimahalle, Ankara, Turkey Phone: +90 312 2553346
GMDN CODE	47032
Conformity Assessment Route	Annex II. Section 3
Products	MODUS Extracorporeal Shockwave Therapy System (ESWT)
Model	MODUS
Classification	IIb, MDD 93/42/EEC Appendix - IX Rule 9
We hereby declare that above mentioned products are comply with 93/42/EEC Medical Devices Regulation and include annex 2007/47/EC. All relevant supporting documentation is kept by the manufacturer.	
EU Regulations / Standards Applied	1. 93/42 / EC Medical Devices Directive, with amendments to 2007/47 /EC Directive 2 . TS_EN_60 601-1 3 . TS_EN_60 601-1-2 4. TS_EN_60601-1- 6 5 . TS_EN_623 6 6-1 6 . TS_EN_6184 6 7 . TS_EN_1 0993-5 8.TS_EN_ISO_1 0993-10
Notified Body	KIWA MEYER CERTIFICATION SERVICES INC. (CE1984) İTOSB 9. Cad. No: 15 Tepeören, 3 4957 Tuzla- İstanbul Türkiye
CE Certificate	1984-MDD-20-657
CE Marking Start/Finish	7 May 2021- 27 May 2024
Signature / Declaration Date /Place	Mehmet İNCE Company Manager  İNCELER MEDİKAL HİZ. SAN. TİC. LTD. ŞTİ. İvedik Organize San. Böl. Halkın San. Sit. 22. Cad. 1495. Sok. No: 9 Ostim - Yenimahalle / ANKARA Tic. Sic. No: 275347 / M.D. 4703 661 350 Tel: (0312) 255 33 47 Fax: (0312) 255 33 47 E-mail: info@incelermedikal.com Web: www.incelermedikal.com