CERTIFICATE

EC CERTIFICATE

Annex II excluding section 4 of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number

CE-MDD-0009/05/2018/01/RC

Manufacturer	:	IMD Tıbbi Ürünler Ve Dış Ticaret Ltd. Şti.
Address	:	Orhan Gazi Mah. ISISO Sanayi Sitesi 13.yol Sk. V-2 Blok No:20 Esenyurt / Istanbul / Turkey
Product(s)	:	1.External Fixators - Unilateral External Fixator Set with Rail System - Multiaxial Deformity Hybrid External Fixator - Tubuler Fixator - Deformity External Fixator 2.Orthopaedic Trauma Implants - Plates, - Screws, - Nails
Model(s)	:	Please see 2nd, 3rd and 4th pages for details of product.
Report Number	:	CE-MED-0155-01, CE-MED-0155-02, CE-MED-0155-03 CE-MED-0155-04, CE-MED-0155-05, CE-MED-0155-06 CE-MED-0155-07, CE-MED-0155-08, CE-MED-0155-09 CE-MED-0155-10, CE-MED-0155-11, CE-MED-0155-12 CE-MED-0155-13, CE-MED-0155-14, CE-MED-0155-15 CE-MED-0155-16, CE-MED-0155-17, CE-MED-0155-18 CE-MED-0155-19, CE-MED-0155-20, CE-MED-0155-21 CE-MED-0155-22, CE-MED-0155-23
First Issue Date and Place **Recertification and Place**	:	2018.05.11 & Istanbul 2021.05.25 & Istanbul
Revision Number and Date	:	00 / --
Validity Date	:	2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s).

Özlem Vicdan Akdağ
Chairman

NOTICE BELGELENDİRME MUAYENE VE DENETİM HİZ. A.Ş. • NB 2764

NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.

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