SHARPLINE

EC DECLARATION OF CONFORMITY

Full quality assurance procedure

No:TD05-02-009 / 20190206-002
Samsun 02.2019

Manufacturer:	Sharpline Medical Ic ve Dis Ticaret Ltd.
Manufacturer's Adress:	Hancerli Mah. Derviszade Sk. No:6/4 55020 Ilkadim, SAMSUN, TURKEY
Medical Device Product Name:	Surgical Motor Systems Electrical and Battery Operated
Model Name:	Sharp X
Classification:	Enclosure IX rule 2 and rule 9, class IIA
Notified Body	
Name:	Kiwa Certification Services Inc.
Adress:	ITOSB 9. Cadde No:15 Tepeören Tuzla, İstanbul, TÜRKİYE
No:	1984

GMDN Code and Term:	[58187] Surgical Drill System multifunctional rechargeable battery/electrical [58188] Surgical Saw System rechargeable battery/electrical

We declare under our sole responsibility, that the medical device of class IIa, to which this declaration relates are in conformity with the provisions of the Council Directive 93/42/EEC (2007/47/EC). Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied. The medical devices are in conformity with the essential requirements of Annex I of the EEC directive. The conformity assessment procedure was performed according to Annex II (class IIa)of the EEC directive.

Standards and Directives Applied:	93/42/EC	EN 60601-1:2006	EN 60601-1-2:2015
	EN 60601-1-6:2010/	EN ISO 15223-1:2016	EN ISO 14971:2012
	EN 62366-1:2015	EN 1041:2008	

Notes: These standards do not necessarily apply to all parts of the product Sharp X and its accessories.

Authorides Signatory:

Murat BAHADIR , Founder - CEO

Date: 29.02.2019

SHARPLINE MEDİKAL İTH. VE DIŞ TİC. LTD. ŞTİ. Hancerli Mah. Derviszade Sk. No:6/4 Tel/Fax: 0362 447 02 00 Ilkadim/SAMSUN Gazilar V.D. No: 769 089 5833 Mersis No: 0769-0895-8330-0001

DD-01R(01) 06.06.2016

Digitally signed by Botnaru Tatiana
Date: 2021.07.05 16:10:00 EEST
Reason: MoldSign Signature
Location: Moldova