CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-102

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

SHARPLINE MEDIKAL IC VE DIS TICARET LIMITED SIRKETI

Hancerli Mah. Derviszade Sk. No: 6/4 Ilkadim SAMSUN-TURKEY

Product: Electrical and battery operated surgical motor system
Model Name: Sharp X

Product: High speed surgical motor system
Model Name: HSM, HSM Micro

Product: Electrical and pneumatical surgical motor systems
Model Name: Electrical Control Unit (M6-034), Pneumatic Surgical Motor

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa Certification Services for details.

Report Number: M.3608.09
Date of first issue: 05 July 2011
Date of last issue: 28 May 2019
Revision Number: 07
Expiry Date: 27 May 2024

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

28 May 2019, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
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Digitally signed by Jighili Tatiana
Date: 2021.06.25 17:28:33 EEST
Reason: MoldSign Signature
Location: Moldova

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
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Mersis No: 0769-0895-8330-0001

DD-01R(01) 06.06.2016