ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 101882 0002 Rev. 00

Manufacturer: **Lotus Surgicals Pvt Ltd**
Khasra No. 1051/ 1&2,Twin Industrial Estate, Selaqui
248197 Dehradun, Uttarakhand
INDIA

EC-Representative: Obelis s.a
53, Boulevard General Wahis, 1030 Brussels, BELGIUM

Product Category(ies): **Ultrasonic Surgical System**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: IND2018056

Valid from: 2019-07-15
Valid until: 2024-05-26

Date, 2019-07-15

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Facility(ies):

Lotus Surgicals Pvt Ltd
Khasra No. 1051/ 1&2,Twin Industrial Estate, Selaqui, 248197
Dehradun, Uttarakhand, INDIA

-/-

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