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

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 105648 0002 Rev. 00

Manufacturer:

Jai Surgicals Limited
B-3, Infocity
Sector 33-34
Gurgaon, Haryana 122001
INDIA

Product Category(ies):

Class IIa medical device: Surgical Blades (Sterile & Non Sterile) in Carbon Steel & Stainless Steel, Disposable Scalpels, Sterile & Non-Sterile (Surgical Blades fitted on Disposable handle with Blade Guard), Retractable Safety Disposable Scalpels (Sterile & Non Sterile) in Stainless Steel with Steadfast Disposal Lock, Protective Shield Safety Disposable Scalpels (Sterile & Non Sterile) in Stainless Steel with Steadfast Disposal Lock, Dermal Curette (sterile & Non sterile) in Stainless Steel, Sterile Biopsy Punches in Stainless Steel (with and without plunger).

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.: IND2019091

Valid from: 2020-05-26
Valid until: 2024-05-26

Date, 2020-05-26

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany