



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 I in sterile conditions, sterilized systems or procedure packs)

No. G1S 105648 0003 Rev. 00

Manufacturer:

Jai Surgicals Limited

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

Product Category(ies):

**Sterile Stitch Cutter Blades in Carbon Steel & Stainless Steel, Sterile
Stitch Cutter on a Disposable Handle with Stainless Steel Blade with
Blade guard, Sterile Safety Stitch Cutter on a Disposable Handle with
Stainless Steel Blade with Steadfast Disposal Lock.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. 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