



EC CERTIFICATE

Niraj Industries Pvt. Ltd.

177/25, Ballabgarh, Faridabad, India- 121004

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Design, manufacture and inspection of Sterile single use medical devices

Device Classification:

Class IIa

Device Descriptions:

Scalpels, Surgical Blades and Blade Management System

Model Type:

Scalpel

Surgical Blades

Blade Management System

We hereby declare that an examination of the full quality assurance system has been carried out per report 11945818, following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required.

File Number A28653
Certificate No. 890.171219

Cycle Start Date 28 June 2017
Effective Date 19 December 2017
Expiry Date 27 December 2018

Authorised by

Itoro Udofia
Certification Manager

For and on Behalf of UL International (UK) Ltd

Notified Body

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