Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System

No. 20 0161 QS/NB

The quality system of manufacturer

Nebula Surgical Pvt. Ltd.

"Nebula" 5th Floor, Narmada Park-3, Vidyakunj Society Main Road, Opp. Kings Height Appt., Amin Marg, Rajkot 360 005 (Gujarat) India

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Orthopaedic Implants and Spinal Implants

The Notified Body No. 1023 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 subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2020-04-07
Valid until: 2024-05-27
First Issued: 2020-04-07
Revision: -

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Date: 2020-04-07

Mgr. Jiří Heš
Representative of the Notified Body No. 1023