



Notified Body 1023

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

EC Certificate - pilna kokybės užtikrinimo sistema No. 11 0673 QS/NB

## EC Certificate - Full Quality Assurance System

### No. 11 0673 QS/NB

Gamintojo kokybės sistema

The quality system of manufacturer

**Samay Surgical** Samay Surgical

Survey No. 212, Plot No. 6, Nr. Patidar Plastic,  
NH-BB, Veraval

(Shapar) - 360 024, Dist. Rajkot, Gujarat, India

**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval  
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

buvo sertifikuota kaip atitinkanti reikalavimus

has been certified as meeting the requirements of

Directive 93/42/EEC

### Directive 93/42/EEC

**on medical devices, Annex II excluding (4)**

Pagal medicinos direktyvą šių produktų kategorijoms:

for the following product category(ies):

Ortopediniai implantai, stuburo implantai

**Orthopaedic Implants, 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.

Galioja nuo: 2020-03-24

**Valid from:** 2020-03-24

**Valid until:** 2024-05-27 Galioja iki: 2024-05-27

**First Issued:** 2011-08-09

**Revision:** c

Peržiūra: c

Data: 2020-03-24

Date: 2020-03-24



*Paul Vg*  
Mgr. Jiří Heš

Representative of the Notified Body No. 1023

Notifikuotosios įstaigos atstovas Nr.1023