ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 15 06 72288 005

Manufacturer:

NISO Biomed S.r.l.
Via Ippolito Nievo, 25
10153 Torino
ITALY

Facility(ies):

NISO Biomed S.r.l.
Via Ippolito Nievo, 25, 10153 Torino, ITALY

Product Category(ies):

Automatic device for the real-time detection of gastroduodenal diseases equipped with a perendoscopic irrigation system

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.: ITA262313

Valid from: 2015-10-07
Valid until: 2020-10-06

Date, 2015-10-05

Hans-Heiner Junker

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

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