



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 17 09 72288 007

Manufacturer: NISO Biomed S.r.l.

Via Sandro Botticelli, 151
10154 Torino
ITALY



Facility(ies):

NISO Biomed S.r.l.
Via Sandro Botticelli, 151, 10154 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.: ITA973620

Valid from: 2017-11-10

Valid until: 2020-10-06



Date, 2017-11-10

Stefan Preiß

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

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