



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. 17 0222 QS/NB

The quality system of manufacturer

SPATZ FGIA Inc.

15 Cuttermill Road # 147, Great Neck, New-York 11021, USA

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):

Balloon gastric appetite suppressing device


Trade name: Spatz3 Adjustable Balloon System®

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: 2017-05-12
Valid until: 2022-05-11
First Issued: 2017-05-12
Revision: -

Date: 2017-05-12




RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023