EC Certificate Full Quality Assurance System: Certificate BE13/223575197

The management system of

Tobrix B.V.

Van Dijklaan 27
5581 WG Waalre, The Netherlands

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Sterile catheters for endovenous laser ablation (peripheral applications)
Sterile baskets for kidney stone removal.
Sterile surgical laser fibers for use in laser surgery applications

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 10 July 2019 until 11 May 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 11 April 2019
Issue 9. Certified since 09 July 2013

Certification is based on reports numbered BE/AND 12/1312.QMD

Authorised by

Jonathan M. Hall

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0215