



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
 (Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 02 98215 001

Manufacturer: **Exact Medical Manufacturing, Inc.**
 4917 William Street
 Lancaster NY 14086
 USA



EC-Representative: **Exact Medical Manufacturing B.V.**
 Kerkstraat 35
 5253 AN NIEUWKUIJK
 THE NETHERLANDS

Product Category(ies): **Sterile Surgical Gowns, Sterile Surgical Drapes, Sterile Equipment Covers and Sterile Scope Warmers.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 72123265

Valid from: 2017-03-14

Valid until: 2022-03-13



Date, 2017-03-14

Stefan Preiß

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



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 02 98215 001

Facility(ies):

Exact Medical Manufacturing, Inc.

4917 William Street, Lancaster NY 14086, USA