



**Sterile Equipment
Cover CE Technical File**

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Effective Date	2016-07-15

EC Declaration of Conformity

Manufacturer:

**Exact Medical Manufacturing, LTD.
4917 Williams Street
Lancaster NY 14086**

Who's single Authorized Representative:

**Exact Medical Manufacturing B.V.
Kerkstraat 35,5253 AN NIEUWKUIJK, THE
NETHERLANDS**

Facilities:

1)Exact Medical Manufacturing, 4917 Wliiams St, Lancaster, NY

We, the manufacturer, herewith declare that the products

- Sterile Equipment Cover Surgical Disposable-UMDNS-Code:15646
- Sterile Gowns Operating Room Disposable-UMDNS-Code:11901
- Sterile Drape Surgical Disposable - UMDNS-Code:15646
- Scope Warmer Disposable - UMDNS-Code:15610

Meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class 1 Sterile according to Annex IX of the Directive 93/42/EEC.

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

**TÜV SÜD Product Service GmbH
Ridlerstr. 65, 80339, München, Germany**

CE-certificate No.: GS2 17 02 98215 001

Issue date: 2017-03-14

Valid until: 2022-03-13

Following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC

Name

Ryan Power

Position

Vice President

date

Thursday, January 11, 2018

Location

4917 William St
Lancaster, NY 14086

The above mentioned declaration of conformity is exclusively under the responsibility of

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