

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 16 12 57451 036

Manufacturer:

Vogt Medical Vertrieb GmbH

Rüppurrer Str. 1A Haus B

76137 Karlsruhe GERMANY

Facility(ies):

Vogt Medical Vertrieb GmbH

Rüppurrer Str. 1A Haus B, 76137 Karlsruhe, GERMANY

Product

Category(ies):

Sterile disposable surgical clothes Sterile disposable gynecology sets

Sterile disposable urinal bags

Sterile disposable syringes without needles

Sterile disposable vaginal specula

Sterile disposable spikes

Sterile disposable gynecology collectors

Sterile 3-way stopcocks

Sterile disposable extension sets

Sterile disposable surgical draping sets

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.:

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2020-12-06

Date, 2017-02-15

Stefan Preiß

0405-27687-36109

 $T\ddot{\text{U}}\text{V}$ $S\ddot{\text{U}}\text{D}$ Product Service GmbH is Notified Body with identification no. 0123

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