

## EC Certificate

## **Production Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)

No. G2 15 02 55729 008

Manufacturer:

Top Glove Sdn. Bhd.

Lot 4969, Jalan Teratai Batu 6

Off Jalan Meru

41050 Klang, Selangor D. E.

MALAYSIA

**EC-Representative:** 

**Top Glove Europe GmbH** 

Bliersheimer Str. 80 D-47229 Duisburg **GERMANY** 

Product Category(ies): Latex and Nitrile Surgical Powder free

Glove, Sterile

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No .:

MYQMH0414002-721410116

Valid from:

2015-02-19

Valid until:

2020-02-18

Date, 2015-02-26

Hans-Heiner Junker



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

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