

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60084665 0001

Report No.: 21195011 001

Manufacturer: OMRON Healthcare Europe B.V.
Scorpius 33
2132 LR Hoofddorp
Netherlands

Products: Aspects of manufacture concerned with conformity of the products with the metrological requirements

Products: peak flow meters

Replaces Approval, Registration No.: DD 60074580 0001

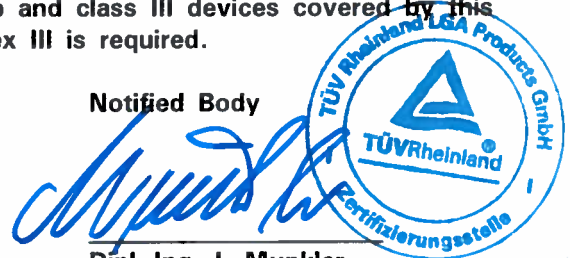
Expiry Date: 2018-04-16

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2013-04-17

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Notified Body



Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.