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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 025703 0035 Rev. 01**

**Manufacturer:** **CHEST M.I., INC.**  
3-25-11 Hongo, Bunkyo-ku  
Tokyo  
113-0033 JAPAN

**EC-Representative:** **Medical Device Safety Service GmbH**  
Schiffgraben 41,  
30175 Hannover,  
GERMANY

**Product Category(ies):** **Spirometers, Pulmonary Function Analyzers and Accessories**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** **JAQ235034682**

**Valid from:** **2019-01-11**  
**Valid until:** **2024-01-10**

**Date,** 2018-10-19

Stefan Preiß

TÜV SÜD  
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**Facility(ies):**

**CHEST M.I., INC.**  
 3-25-11 Hongo, Bunkyo-ku, Tokyo, 113-0033 JAPAN

**CHEST MIYAGI FACTORY**  
 2-3-1 Yoshioka Higashi, Taiwa-cho, Kurokawa-gun,  
 Miyagi, 981-3627 JAPAN

**CHEST IBARAKI OFFICE**  
 3-37-1 Uchimoriyamachi Kinunosato, Joso, Ibaraki,  
 303-0046 JAPAN

-/-

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