



## EU DECLARATION OF CONFORMITY

Distributed by: JBM CAMPLLONG, S.L.U.

Address: CIM La Selva – Crta. Aeroport Km 1.6 Nave 2.2, 17185 Vilobí d'Onyar, Girona

CIF: ESB17419292

Product's description: Single-use medical face masks

Manufacturer's reference: 12447

Distributor's reference: 53907

The declaration object complies with the directives 93/42/EEC ( Medical device Directive); and the following standards:

Standard	Title	Edition/Date
EN ISO 13485	Medical devices – Quality management systems - Requirements for regulatory purposes.	2016

Signed by:



Eduard Godoy

Purchasing department director

Girona, 26th August, 2021



Product Service

# Certificate

No. Q5 071789 0042 Rev. 02

**Holder of Certificate:** **Conod Medical Co., Limited**

No. 11 Hongfeng Road  
 Deimao Industrial Park, Culi Town  
 215532 Changshu City, Jiangsu Province  
 PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**

Design and Development, Production and Distribution of Dialysis Kits, Suture Remove Kits, Dressing Change Trays, Non-woven Ball Kits, Urine Bag(with and without Gloves Pack/with and without Straps), Feeding Set, Tracheostomy Care/Cleaning Kits, Irrigation Trays, Suction Connecting Tubes with and without Yankauer, Urinary Catheterization/Collection Kits with and without Prefilled Syringes, Suction Yankauer, Wound Drainage Systeme with and without Trocar, Silicone Bulb Evacuators with and without Drains and Trocars, Vaginal Dilators, Specimen Containers, Urethral Catheters, Ear/Ulcer Syringes, CPR Face Masks, Suction Canisters, Suction Liners, Pre-filled Syringes, Wet Skin Prep. Trays, Pleura-Function-Sets, Forceps, Urine Meters(w/wo Urine Sampling Blunt Cannular), Pre-filled Syringe with Lubricant Jell, Anaesthesia Mask, Enteral Feeding Set(Bag), Irrigation Syringe, Nutrition Bottles, Enema Set(Kits), Drainage Bags, IV Start Kit, Laceration Tray, Fecal Management System, Straps Set, Catheter Valve, Medical Face Masks

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH2050401

**Valid from:** 2020-05-29

**Valid until:** 2021-12-31

**Date,** 2020-05-28

Christoph Dirke  
 Head of Certification/Notified Body



## Certificate

**No. Q5 071789 0042 Rev. 02**

### **Applied Standard(s):**

EN ISO 13485:2016  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2016)  
 DIN EN ISO 13485:2016

### **Facility(ies):**

Conod Medical Co., Limited  
 No. 11 Hongfeng Road, Baimao Industrial Park, Guli Town, 215532  
 Changshu City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Conod Medical Co., Limited  
 No. 2 Zengfu Road, Baimao Industrial Park, Guli Town, 215532  
 Changshu City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Conod Medical (Shuyang) Co., Limited  
 Two side of Jinhua Road, North side of Yuhuan Road, South side of  
 Wenzhou Road, Shuyang Development Zone, 223600 Shuyang  
 City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA