SAO Y BẢN CHÍNH
Ngày 06 tháng 05 năm 2022

GETINGE

File No.:RA-DoC 017.03

EC Declaration of Conformity

Manufacturer:

MAQUET (Suzhou) Co., Ltd.
No.158 Fangzhou Road, Suzhou Industrial Park, 215024 Suzhou, China

whose single Authorized Representative:

MAQUET S.A.S.
Parc de Limère Avenue de la Pomme de Pin, CS 10008 Ardon 45074 Orléans cedex 2, France

GIÁM ĐỐC
Nguyễn Quý Khải

We, the manufacturer, herewith declare that the products.

Brand: MAQUET
Product Category: MEDICAL CEILING SUPPLY UNITS
Type/Model: MODUEVO
UMDNS-Code: **16001**; *GMDN-Code:* **35630**

Meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II.3 of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 60126668 0001
Effective date: 2018-04-22
Expiry date: 2023-04-21

Following the procedure relating to the EC Declaration of Conformity set out in Annex II.3 of Directive 93/42/EEC

This declaration of conformity is valid in connection with the release document (including attached standards list) for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the sole responsibility of

Maquet (Suzhou) Co., Ltd
No.158 Fangzhou Road, Suzhou Industrial Park, 215024 Suzhou, China

Suzhou 2018-04-09
Place , date

Quality Manager Helena Lu
Legally binding signature, Function

File No.: RA-DoC 017.03

Standards list

The above mentioned product (s) meets all the provisions of the directive 93/42/EEC and 2007/47/EC which apply to it.

No.	Standard Number	Standard Title
1	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
2	EN ISO 5359:2014	Low-pressure hose assemblies for use with medical gases
3	EN ISO 7396-1:2007 +A3 2013	Medical gas pipeline systems - Part 1:Pipeline systems for compressed medical gases and vacuum
4	EN ISO 7396-2:2007	Medical gas pipeline systems - Part 2:Anaesthetic gas scavenging disposal systems
5	EN ISO 9170-1:2008	Terminal units for medical gas pipeline systems – Part 1: Terminal units for use with compressed medical gases and vacuum
6	EN ISO 9170-2:2008	Terminal units for medical gas pipeline systems – Part 2: Terminal units for anaesthetic gas scavenging systems
7	EN ISO 11197:2016	Medical supply units
8	EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
9	EN ISO 15001:2011	Anaesthetic and respiratory equipment – Compatibility with oxygen
10	EN ISO15223-1:2016	Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied Part 1: General requirements.
11	EN 60601-1:2006/A1:2013	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
12	EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral standard: Electromagnetic compatibility- requirements and tests.
13	IEC 60601-1-6:2013	Medical electrical equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral standard: usability
14	EN/IEC 60601-1-9:2007	Medical electrical equipment- Part1-9: General requirements for basic safety an essential performance- collateral standard: requirements for environmentally conscious design
15	BS EN 62304-2006+A1:2015	Medical device software – Software life – cycle processes
16	IEC 62366-1:2015	Medical device – Application of usability engineering to medical devices

All the standards are current version unless otherwise stated.
End of document.