

Manufacturer:

whose single Authorized Representative:

SCW MEDICATH LTD.

**OBELIS S.A.** 

NO.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen,

GON 保密文件 SCW Confidential Bd. Général Wahis 53 1030 Brussels, Belgium

518116, Guangdong, P.R. China

We, the manufacturer, herewith declare that the products

**Connecting Tubings** 

Models: 0.12inch, 0.15inch

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

The medical device has been assigned to class IIa according to Annex IX Rule 2 of the Directive 93/42/EEC. It bears the mark

**€** 0197

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

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

> TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg **Deutschland**

Certificate No.: HD 60144232 0001 Issue date: 26.05.2020 Expiry date: 26.05.2024

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

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

益则这 SCW R密文件 SCW Confidential NO.4, Baolong 6th Road, Baolong Industrial Town, Longgang
District, Shenzhen, 518116, Guangdong B.B. China

Shenzhen, 2020/07/16

Place, date

Mitiam Xe RA Legally binding signature, Function

**EC Declaration of Conformity** SCW-MDTF-CT-DOC A.6