EC Declaration of Conformity

Manufacturer:

SCW MEDICATH LTD.

NO.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116, Guangdong, P.R. China

whose single Authorized Representative:

OBELIS S.A.

Bd. Général Wahis 53
1030 Brussels, Belgium

We, the manufacturer, herewith declare that the products

Postpartum Balloon
Models: PPB-24F,PPB-24F-II

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 7 of the Directive 93/42/EEC. It bears the mark

CE 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

SCW MEDICATH LTD.
NO.4, Baolong 6th Road, Baolong Industrial Town,
Longgang District, Shenzhen, 518116, Guangdong, P.R. China

Shenzhen, 2020/07/16
Place, date

Miriam Xie, RA
Legally binding signature, Function