Rosesta Medical BV
Mr Treublaan 7
1097 DP, Amsterdam
The Netherlands

DECLARATION OF CONFORMITY

We, Rosesta Medical B.V., hereby declare that the distributed hereby declare that the CE marked products specified below meet the relevant provisions of Annex VII of the Council Directive 93/42/EEC of 14 June 1993, including all amendments, concerning medical devices and all harmonized standards which are applicable to the object, as published in the Official Journal of the European Communities.

The FERTI·LILY Conception Cup is moulded at Silcoplast A.G., located at Luchten 75, 9427 Wolfhalden, Switzerland under ISO 13485:2016 certification.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class I, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality Management System approved for the manufacture and final inspection of the products concerned, in accordance with Annex V of the EC-Directive.

Amsterdam, 16 April 2020

Rosesta Medical BV
Robert Stal
CEO

Product range

FERTI·LILY Conception Cup First batch: 7233, released 20th of June, 2019

Description of change		
Version	**Date**	**Reason for change**
1.0	05 Feb 2019	First Draft - Premarket
2.0	20 June 2019	Update for postmarket
3.0	18 Dec 2019	Addition of Silcoplast as production site
4.0	16 April 2020	Update after additional packaging site Valuepack