

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

SRN: NL-MF-000001495

DECLARATION OF CONFORMITY

We, Rosesta Medical B.V., also doing business as “FERTI-LILY”, hereby declare that the distributed CE marked products specified below meet the relevant provisions of the Council Regulation (EU) MDR 2017/745 of 05 April 2017, 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 provision of the Regulation (EU) MDR 2017/745 for medical devices which apply to them.

This declaration of conformity is issued under the sole responsibility of Rosesta Medical BV and 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 IX of the EC-Regulation.

All supporting documentation is retained at the premises of the manufacturer.

Amsterdam, 15 OCT 2021
Expires: 15 October 2026



Rosesta Medical BV
Robert Stal
CEO

Product range

FERTI-LILY Conception Cup
Basic UDI-DI (GMN)

First batch: Batch 9276 – all products released after 20 May 2021
8720589524FLCC00CU

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
5.0	10 Nov 2020	Update DoC after complying to Regulation (EU) MDR 2017/745
6.0	20 JAN 2021	Update DoC to correct UDI-DI check pair from FQ to JU.
7.0	25 JAN 2021	Update DoC. Correction typo DOC.
8.0	25 JAN 2021	Update DoC. Correction typo DOC.
9.0	18 MAY 2021	Update with first MDR production batch.
10.0	14 July 2021	Include FERTI·LILY Tradename, also doing business as.
11.0	15 Oct 2021	Correcting a mistake in the Basic UDI-DI. Incorrect company prefix used and add expiry date