

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

DECLARATION OF CONFORMITY

We, Rosesta Medical B.V., hereby declare that the distributed 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.

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, 19 May 2021



Rosesta Medical BV
Robert Stal
CEO

Product range

FERTI·LILY Conception Gel

First batch: 1070971, released 19 May 2021

Description of change		
Version	Date	Reason for change
1.0	10 Sep 2020	First Draft - Premarket
2.0	19 May 2021	Update upon first release