

MANUFACTURER: *Noventure S.L.***ADDRESS:** *Avenida Diagonal 549, 5ª planta. 08029 Barcelona (Spain)***DECLARE UNDER THEIR SOLE RESPONSIBILITY THAT THE PRODUCT:****Product Name:** ROTER CYSTICARE UTIPRO PLUS capsule**REF: (SAP code)*** 1XXXXXX**Intended use:**

The device is intended for the control and prevention of urinary tract infections produced by pathogens such as E Coli and other gram (-) bacteria normally involved in the aetiology of urological infections.

GMDN code: 58028**Classification and rule according to Annex IX of MDD 93/42/EEC**Class III
Rule 17

All devices manufactured utilizing animal tissues or derivatives rendered non-viable are class III except where such devices are intended to come into contact with intact skin only.

* On the basis of the criteria used for the codification presented by the Company and filed by this Notified Body, the above code/s has/have the following meaning:

1: 1 digit, it represents the finished product

XXXXXX: 6 digits, it represents a numeric code between 0 to 999999 assigned randomly by SAP; this system assures one different code per product, presentation and territory

CONFORMS WITH THE REQUISITES OF THE DIRECTIVES:**MDD 93/42/CEE and the amendment 2007/47/EC**EU Medical Device Directive, *as transposed into national laws***Conformity assessment route***Annex II as per MDD 93/42/EEC***Notified Body** (number and address)

Code number: 0373

Address: *Istituto Superiore di Sanità. Viale Regina Elena, 299 - 00161 Rome. Italy.***EC Certificate num.**

EC Design examination certificate: EPG-0086-17, valid until 21/12/2022

Full Quality Assurance System: QCT-0069-17, valid until 21/12/2022

Relevant harmonised standards:*EN ISO 14971:2012, EN ISO 13485:2016+/AC:2016, EN ISO 10993-1:2010*

Additional information: *The manufacturer undertakes to maintain and make available to the Competent Authorities the technical documentation specified in Annex II of the Directive 93/42/EEC, and the amendment 2007/47/EC, and manufacturing records for a period of at least ten (10) years after the last device has been placed in the market.*

PLACE & DATE:

Barcelona, 07/01/2020

STAMP AND SIGNATURES:**NOVENTURE, S.L.**
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08029 Barcelona - Spain

Rev: TF Utiplus rev 8

Paula Martínez
Management Representative