EC DESIGN-EXAMINATION CERTIFICATE

Number: 92494DE01

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

Prosan International B.V.

IJsselburcht 3
6825 BS Arnhem
The Netherlands

For the product

Copper intra uterine devices 300 and 380

Documents, that form the basis of this certificate:

Certification Notice 92494CN, initially dated 28 April 1999
CE Marking of Conformity 92494CE01
Addendum, initially dated 23 February 2016

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 23 February 2016
Reissued: 1 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 92494DE01

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Copper intra uterine devices 300 and 380

Issued to:

Prosan International B.V.
IJsselburcht 3
6825 BS Arnhem
The Netherlands

This certificate covers the following product(s):

CU SAFE 300
CU SAFE 300 D
CU SAFE+ 300
CU SAFE+ 380

Initial date: 23 February 2016
Revision date: 6 March 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

ADDENDUM

Belonging to certificate: 92494DE01

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Copper intra uterine devices 300 and 380

Issued to:

Prosan International B.V.
IJsselburcht 3
6825 BS Arnhem
The Netherlands

This certificate covers the following product(s):

Flexi-T 300
Flexi-T 300 D
Flexi-T+ 300
Flexi-T+ 380

Initial date: 23 February 2016
Revision date: 6 March 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344