CERTIFICATE

Number: 2231906

The management system of:

Prosan International B.V.

IJsselburcht 3 6825 BS Arnhem The Netherlands

Manufacturer DUNS 411964562

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009 Canada: Medical Devices Regulations - Part 1- SOR 98/282

Scope:

Design and development, manufacture, sales and distribution of copper bearing intrauterine contraceptive devices.

Certificate expiry date: 2022-12-01
Certificate effective date: 2019-12-01
Certified since: 2019-12-01

DEKRA Certification B.V.

B.T.M. Holtus Managing Director J.A. van Vugt Certification Manager

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The validation of the validity of this certificate can be checked through DEKRA's website using the following link: https://www.dekra-product-safety.com/en/certified-organizations

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

