Arnhem, 20-1-2022

To whom it may concern

Prosan International B.V., as a manufacturer of medical devices, is preparing for CE registration of the Flexi-T copper intrauterine devices under EU MDR 2017/745. The current CE certificate under directive 93/42/EEC is valid until 26th May 2024.

Prosan will be using the transitional provisions, as defined in EU MDR 2017/745, article 120. The planning for the transition by Prosan is as follows:

- On 26th May 2021, Prosan will have implemented the requirements of this Regulation relating to post- market surveillance, market surveillance and vigilance;
- The requirement of registration of economic operators and of devices shall be fulfilled as and when the Eudamed database is operational;
- By 26th May 2021, Prosan will have implemented Unique Device Identification (UDI);
- By August 2023, Prosan aims to have the Flexi-T copper intrauterine devices registered under EU MDR 2017/745.

C. van der Zaal

QARA Officer.