

Mezzovico-Vira, 07<sup>th</sup> February 2022

To whom it may concern

We hereby declare that Polydentia Class I medical devices are not accompanied with Instruction for use because the products can be used safely and effectively without the provision of such instructions as per Annex I, Section 23.1(d) of European Medical Device Regulation EU 2017/745.

Sincerely,



Simona Binda Rossetti

Quality and Regulatory Affairs Manager