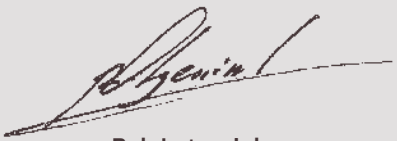
EU DECLARATION OF CONFIRMITY

Manufacturer:	Huka B.V.
Address:	Münsterstraat 13, 7575 ED Oldenzaal, The Netherlands
SRN: Single Registration Number	NL-MF-000003494
Product type:	Tandem
Device name:	Copilot 26
Basic UDI:	8720589794092
Risk class:	Class 1
Conformity assessment route:	Huka uses the following procedures for the CE marking of their products according to Regulation MDR 2017/745: Class 1: according to (EU) 2017/745 Annex VIII

This declaration of conformity is issued under the sole responsibility of Huka. We hereby declare that the medical device (s) specified above comply with the provisions of Regulation (EU) MDR 2017/745 for medical devices.
This declaration is supported by the certified quality system according to ISO 13485: 2016 issued by "het Keurmerkinstituut" and the relevant sections of the following harmonized standards: EN-ISO 14971: 2012 and EN 12182: 2012.
All supporting documentation is kept on the manufacturer's premises.

Signed on behalf of Huka on April 6, 2023 at Oldenzaal, The Netherlands



Rob Lotgerink
Managing Director

CE

Form Name: MDR CE Declaration of Conformity ENG v20210521