

EU DECLARATION OF CONFIRMITY

| | |
|---|---|
| Manufacturer: | Huka B.V. |
| Address: | Münsterstraat 13, 7575 ED Oldenzaal, The Netherlands |
| SRN: <small>Single Registration Number</small> | NL-MF-000003494 |
| Product type: | Duo bike |
| Device name: | Orthros |
| Basic UDI: | 8720589794016 |
| 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:



Rob Lotgerink
Managing Director

Place and date:

Oldenzaal, 21 May 2021