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|  | <b>EC - DECLARATION OF CONFORMITY</b> | File: F.10.004<br>Version: 01<br>Status: 20.02.2026 |
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## EC - DECLARATION OF CONFORMITY

For the medical devices described below

|                                                                     |                                                                                                                                                                                                                                   |               |               |                |                 |
|---------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------------|----------------|-----------------|
| Product group                                                       | Prostasella                                                                                                                                                                                                                       |               |               |                |                 |
| Product name, trade name                                            | Prostasella S                                                                                                                                                                                                                     | Prostasella M | Prostasella L | Prostasella XL | Prostasella RPx |
| Product code, catalogue number                                      | 4HPS001                                                                                                                                                                                                                           | 4HPS002       | 4HPS004       | 4HPS004        | 4HPS005         |
| Basic UDI-DI                                                        | 42700047355J4                                                                                                                                                                                                                     |               |               |                |                 |
| Risk class                                                          | Class I; Rule 1 within Annex VIII of the Regulation (EU) 2017/745 (MDR)                                                                                                                                                           |               |               |                |                 |
| Intended use                                                        | The Prostasella bicycle saddle is an accessory for bicycles and e-bikes designed to provide ergonomic seating support while riding.<br>The special saddle shape is designed to reduce pressure in the perineum and prostate area. |               |               |                |                 |
| Manufacturer                                                        | 4H Entwicklungs GmbH                                                                                                                                                                                                              |               |               |                |                 |
| Address                                                             | Olgastraße 139, 89073 Ulm, GERMANY                                                                                                                                                                                                |               |               |                |                 |
| Single Registration Number (SRN)                                    | DE-MF-000056045                                                                                                                                                                                                                   |               |               |                |                 |
| Standards, Specifications                                           | - Regulation (EU) 2017/745 (MDR)<br>- Medical Devices Implementation Act (MPDG)<br>- DIN EN ISO 9001:2015-11<br>- DIN EN ISO 4210-9:2023-05                                                                                       |               |               |                |                 |
| Conformity assessment procedure (Regulation (EU) 2017/745, art. 52) | Annex IV                                                                                                                                                                                                                          |               |               |                |                 |

The manufacturer with sole responsibility declares that the product meets all applicable requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and its implementation into national laws.

signed on behalf of 4H Entwicklungs GmbH  
Ulm, 2026.07.14

Dr. Horst Hohmuth  
Managing Director

Guido Weingart  
Responsible Person (Article 15/MDR)

