

European Declaration of Conformity to the Medical Device Regulation, (EU) 2017/745

Manufacturer:

AFH Europe Sp. z o.o.

PL. Solny 14/3, 50-062 Wrocław, Poland

This declaration of conformity is issued under the sole responsibility of AFH Europe Sp z o.o.. We hereby declare that the below-mentioned products, which is designed to compensate for an injury or disability, meet the provisions of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the quality system complied with ISO 13485:2016. All supporting documentation is retained at the premises of the manufacturer.

The basic UDI-DI referred to in Annex VI, Part C, will be assigned by the manufacturer to a given device as soon as the identification of that device becomes a requirement based on the UDI-DI system.

Brand Name:

Automation of Humanity

Product Name:

Shower chair

Model(s):

RSC02

Classification Rule:

Rule I, non-sterile and non-active product

Conformity/Assessment Route:

Class I - Self Declaration

GMDN Code:

34936 Chair, bath/shower

The device is designed to compensate for an injury or disability.

Date of Issue:

Signature:

CIUI

Data

· 2022-12-27

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