

Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Warsaw,

N 4 -12- 2024

CERTIFICATE OF FREE SALE No. 727/2024

Based on Article 60 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 (EU OJ L 117 z 05.05.2017, p. 1, as amended) and art. 30 of the Act of April 7, 2022 on medical devices (Journal of Laws of 2024, items 1620, as amended) in connection with the application for a certificate of free sale submitted by:

MyWam Sp. z o.o. (applicant for certificate of free sale)

it is certified that the medical device listed below:

Name of the device

Type

Bath chair Delfi

Size S, Size M, Size L

Notified body certificate number

Basic UDI-DI code

5901122279DelfiA6

manufactured by:

MyWam Sp. z o.o. ul. Lwowska 34, 41-500 Chorzów, Poland (identification of the manufacturer)

on the basis of the statement of the manufacturer is CE marked at the sole responsibility of the manufacturer. The medical device CE marked in conformity with 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 can be placed on the market and put into service in the European Union. Export of the product is not prohibited.

President of the Office

Z upoważnienia Prezesa ZASTEPCA DYREKTORA Departament Informacji o Wyrobath Medycznych

Anna Kulma

ACJI PRODUCTO DILATOR BIGGO

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GDPR - Information on the processing of personal data can be found on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

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