

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

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Warsaw, 2022-11-18

CERTIFICATE OF FREE SALE No. 830 / 2022

President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products 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 (OJ L 117 z 5.5.2017, p. 1) pursuant to art. 30 of the Act of April 7, 2022 on medical devices (Journal of Laws of 2022, items 974) in connection with the application for a certificate of free sale made by the

AKCES-MED SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ

(applicant for certificate of free sale)

certifies that the medical device listed below:

Name of the device

Type

SPECIAL NEEDS STROLLER AURA

AURA 1, AURA 2

Notified body certificate number

Not applicable

Basic UDI-DI code

59038165AURZR

manufactured by:

AKCES-MED SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ JASIONKA 955 B, 36-002 JASIONKA, 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 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

On behalf of the President Vice-President for Medical Devices

Sebastian Migdalski