

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

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Warsaw, 2021-03-01

CERTIFICATE OF FREE SALE No. 102/2022

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 pursuant to art. 67 of the Act of May 20, 2010 on medical devices (Journal of Laws of 2021, items 1565) in connection with the application for a certificate of free sale made by the

Akces-MED Sp. z o.o. (applicant for certificate of free sale)

certifies that the medical device listed below:

Name of the device

Type

Standing frame GENIUS

MODELS: GENIUS 1, GENIUS 2, GENIUS 3

Notified body certificate number

Not applicable

Basic UDI-DI code

59038165GNS27

manufactured by:

Akces-MED Sp. z o.o.

Jasionka 955B, 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