DoC-3-2025-MIRAcle-EN
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Place of issue / date

EU DECLARATION OF CONFORMITY

Manufacturer name: MIRAcle Robert Biegański, Małgorzata Bauer Sp. J.

Manufacturer address: ul. Piotrkowska 145, 90-434 Łódź, Poland (EU)

SRN: PL-MF-000040195

Trade name of the device: Magnifiers

Models: Exigo, Exigo 4U, Spider, Spider 4U, Pulchra Es, Admirabilis, Pearl 5.

Basic UDI-DI: 59050686953POC5

Intended purpose / indications: Magnifiers (electronic magnifiers) are portable electronic devices equipped with a camera and a screen. They use magnification based on relative size and contrast enhancement of up to 70% to facilitate reading by people with low vision who require magnification greater than 6×.

EMDN code: Y210699

Risk class of the device: Class I

Classification rule: Rule 13, Annex VIII to Regulation (EU) 2017/745

Conformity assessment procedure: Annexes II and III to Regulation (EU) 2017/745

This declaration of conformity has been issued under the sole responsibility of and on behalf of the manufacturer. The medical device complies with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Standards applicable to the device:

PN-EN ISO 13485:2016-04
PN-EN ISO 14971:2020-05
PN-EN ISO 20417:2021-10
PN-EN ISO 15223-1:2022-01
PN-EN ISO 10993-1:2021
PN-EN 60601-1:2011

Partner / Owner
Małgorzata Bauer

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Partner / Owner
Robert Biegański

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(Position / Full name / Signature)

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