



EU DECLARATION OF CONFORMITY

Manufacturer:

LIW Care Technology Sp. z o.o.
ul. Golfowa 7
94-406 Łódź, Poland

Hereby declares that

BAFFIN TRIO

size: 1 and 2

bearing CE mark is a Class I medical device, Rule 13 in accordance with Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and fulfills the requirements specified in this Regulation.

The conformity assessment was done according in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Medical device is in conformity with the following harmonized standards:

- PNEN 12182:2012
- PN-EN ISO 14971:2012
- PN-EN 1041+A1:2013-12
- PN-EN ISO 15223-1:2017-02
- PN-EN 60601-1-2:2015-11
- PN-EN ISO 13485:2016

We declare that the product fulfills requirements of the RoHS Directive 2011/65/UE, including all its amendments.

Basic UDI-DI: 5904384015TRIO8P

EU declaration of conformity is issued under the sole responsibility of the manufacturer.

On behalf of the manufacturer:
Tomasz Chmielecki, CEO

Signature:

Manufacturer's seal:

Łódź, 26th of May 2021