EU DECLARATION OF CONFORMITY

Manufacturer:

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

Hereby declares that:

BAFFIN.1

bearing CE mark is a Class I medical device, Rule 1 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 basic 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:

- PN-EN 12182:2012
- PN-EN ISO 14971:2012
- PN-EN 1041+A1:2013-12
- PN-EN ISO 15223-1:2017-02

Basic UDI-DI: 5904384015BAFFIN19K

Baffin.1 is approved to Regulation No. 44 of the Economic Commission for Europe of the United Nations (UNECE) — Uniform provisions concerning the approval of restraining devices for child occupants of power-driven vehicles ('Child Restraint Systems') [2016/1722] - Supplement 10 to the 04 series of amendments.

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

On behalf of the manufacturer:
Tomasz Chmielecki, CEO

Signature:

LIW CARE TECHNOLOGY Sp. z o.o.
94-406 Łódź, ul. Golfowa 7
NIP: 729-266-53-87, REG. 100715121
KRS:0000333719

Łódź, 26th of May 2021

Manufacturer's seal: