

DECLARATION OF CONFORMITY

Manufacturer:

LIW Care Technology Sp. z o.o. ul. Golfowa 7

94-406 Łódź

Hereby declares, that

TravelSit Size: S, M

bearing CE mark is a Class I medical device, Rule 1, in accordance with Annex 9 of the Medical Directive of the European Union MDD 93/42 / EEC and fulfils the basic requirements specified in Annex 1 of this Directive.

The conformity assessment was carried out on the basis of 7 Council Directive 93/42 / EEC.

The product meets the requirements of the Act of 20 May 2010 on medical devices (Journal of Laws 2017 item 211), Regulation of the Minister of Health of February 17, 2016. on essential requirements and conformity assessment procedures for medical devices (Journal of Laws of 2016, item 211).

The product meets the requirements of harmonized standards:

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

On behalf of the manufacturer: LIW Care Technology Sp. z o.o.

Tomasz Chmielecki PREZES ZARZĄDU Łódź, 13th of February 2020.

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