

DECLARATION OF CONFORMITY

Manufacturer:

LIW Care Technology Sp. z o.o.

ul. Golfowa 7

94-406 Łódź, Poland

Hereby declares that

ORTHOPAEDIC SEAT STABILISING BACK AND HEAD FOR CHILDREN THE BAFFIN neoSIT RS

Control manual; size S, M, L

bearing CE mark is a Class I medical device, Rule 1 in accordance with Annex 9 of European Medical Devices Directive 93/42/EEC + 2007/47/EC and fulfills the basic requirements specified in Annex 1 of the Directive.

The conformity assessment was done according to Annex 7 of Directive 93/42/EEC. 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 15223-1:2012

On behalf of the manufacturer: Tomasz Chmielecki, CEO

Signature:

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Łódź, 15 February 2017

Manufacturer's seal:

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