



DECLARATION OF CONFORMITY

Manufacturer:

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

Hereby declares that

THE BAFFIN neoSIT
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 15223-1:2017-02**

On behalf of the manufacturer:
Tomasz Chmielecki, CEO

Signature:

Łódź, 29 May 2018

Manufacturer's seal:

LIW CARE TECHNOLOGY Sp. z o.o.
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