

## **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 15223-1:2012

On behalf of the manufacturer: Tomasz Chmielecki, CEO

Signature:

Łódź, 21 December 2015

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