



DECLARATION OF CONFORMITY

Manufacturer:

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

Hereby declares that

THE BAFFIN AUTOMATIC
Control automatic, size: S,M,L

bearing CE mark is a Class I medical device, Rule 12 in accordance with Annex 9 of European Medical Devices Directive 93/42/EEC 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
PN-EN 60601-1-2:2015-11

We declare that the product fulfills requirements of the RoHS Directive 2011/65/UE, including all its amendments. The conformity assessment was done according to standard PN-EN 50581:2013-03.

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

Manufacturer's seal:

Łódź, 18 July 2017