CE Declaration of conformity

The Manufacturer:

Adaptica Srl
Company

Via San Marco 9/H – 35129 - Padova – ITALY
Address

+39 049 773968
Phone

Declares under its responsibility that the medical device

2WIN

class: IIa, rule 10

Conformity assessment procedure: Annex II.3 93/42/EC Directive (including 2007/47/EC)

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, D-80339 München (N. 0123)

S/N 2WINHG01326 – S/N 2WINHG01375

Meets the essential requirements of Annex I of Medical Devices Directive 93/42/EC (including 2007/47/EC).

This medical device satisfies the applicable harmonized standards.

Technical documents are maintained by the Manufacturer for all the life time of the product and they could be inspected by the Competent Authority.

A post market surveillance system with recall provision is in place.
CE mark starting date 25/10/2013.

Managing Director — **Gianluigi Meneghini**
Name Surname

Signature

PADOVA, 17/10/2016
Place and date

Rev.05-Gen. 2016