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)

EC-Certificate of conformity No. G1 080400 0010 (Instrument for the measurement of binocular and monocular refraction based on infrared photorefraction)

Serial Numbers : from 2WIN000** to 2WIN000****

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.

Legal Representative **Xiangdong He**

Name Surname

Signature

Place and date

Rev.09- 2020 September