

CE Declaration of conformity

The Manufacturer:

CenterVue SpA

Company

Via San Marco 9H, 35129 Padova – ITALY

Address

+39 049 501 8399 / +39 049 501 8398

Phone/fax

Declares under its responsibility that the medical device

DRS

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)

***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: **October 11th 2010.****Management representative****Giuliano Barbaro****CenterVue S.p.A.**Via S. Marco, 9/H
35129 Padova, Italy**centervue** C.F./P.IVA 04288580287

Signature

Name Surname

Padova, 2018-06-27

Place and date