



Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

No. G2 16 04 24169 036

**Manufacturer:** EUROSETS S.r.l.

Strada Statale 12, 143  
41036 Medolla (MO)  
ITALY



**Facility(ies):** EUROSETS S.r.l.

Strada Statale 12, 143, 41036 Medolla (MO), ITALY

**Product Category(ies):** Autotransfusion system, blood processing  
(red blood cell concentration optical sensor,  
electromechanical clamp)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:** ITA272689

**Valid from:** 2016-08-25

**Valid until:** 2019-07-12



**Date,** 2016-08-25

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1