



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 14 12 75234 002

**Manufacturer:** Sterilis Sardegna S.r.l.  
Loc. Cirras snc  
09096 S. Giusta (OR)  
ITALY

**Facility(ies):** Sterilis Sardegna S.r.l.  
Loc. Cirras snc, 09096 S. Giusta (OR), ITALY

**Product Category(ies):** Gauzes: sterile for single use  
tablets folded and laparotomy  
hydrophilic gauzes, with and  
without wire barium

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.:** ITA2367361S

**Valid from:** 2015-06-09

**Valid until:** 2020-06-08



**Date,** 2015-06-09

Hans-Heiner Junker

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

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