



Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 12 33250 012

**Manufacturer:** **CLINI-LAB s.r.l.**  
VIA 2° STRADA 14 Z.I.  
35026 Conselve (PD)  
ITALY



**Facility(ies):** CLINI-LAB s.r.l.  
VIA 2° STRADA 14 Z.I., 35026 Conselve (PD), ITALY

**Product Category(ies):** **Sterile Urine drainage bags**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** ITA1009165

**Valid from:** 2018-02-13  
**Valid until:** 2023-02-12



**Date,** 2018-01-11

Stefan Preiß

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

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