

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 08 29670 029

Manufacturer:

Greiner Bio-One GmbH

Bad Haller Straße 32 4550 Kremsmünster

AUSTRIA

Facility(ies):

Greiner Bio-One GmbH

Bad Haller Straße 32, 4550 Kremsmünster, AUSTRIA

Product

Category(ies):

VACUETTE® Blood Collection System:

VACUETTE® Multiple Use Drawing Needles, including VACUETTE® VISIO PLUS Needles

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.:

713041729 1

Valid from:

2014-08-12 2019-07-31

Valid until:

Hans-Heiner Junker



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

Page 1 of 1

Date,

2014-08-13