

EC DECLARATION OF CONFORMITY

according to annex III of the Directive 98/79/EC of the European Parliament and of the Council of 27. Oct. 1998 on in vitro diagnostic medical devices

Manufacturer:

Greiner Bio-One GmbH

Address:

Bad Haller Str. 32

A-4550 Kremsmünster

AUSTRIA

Production

Greiner Bio-One GmbH

Location:

Bad Haller Str. 32

A-4550 Kremsmünster

AUSTRIA

Product

VACUETTE® Transport Box (VTB)

Classification

Directive 98/79/EC; Other device (all devices except Annex II and self-

testing devices)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and applicable Standards. All supporting documentations are retained under the premises of the manufacturer.

This product has been CE marked since 29 Oct 2003.

DIRECTIVES

Directive 98/79/EC of the European Parliament and of the Council of 27. Oct. 1998 on in vitro diagnostic medical devices

STANDARDS

Standards applicable are: ISO 9001, EN ISO 13485

Place, Date:

ein Kremsmünster, 02. FEB. 2010

Signature:

Gabriele Rose

QM, Regulatory Affairs