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Drawn Date Revision	S. Kälberer 4 December 2009 03	ISO/IEC 17050	greiner bio-one

Declaration of Conformity

In accordance with ISO/IEC 17050

Number of declaration

13-04-8

We Greiner Bio-One GmbH Maybachstr. 2 D-72636 Frickenhausen Germany

hereby declare in our own responsibility that the following products

12X 2XX

Cryo.s™ cryogenic tubes

12X 2XX – XXX

Cryo.s[™] cryogenic tubes with barcode or 2D code

meet our demands on internal documentation of the DIN EN ISO 9001:2000 and DIN EN ISO 13485:2007 and are related to appropriated technical and harmonized Norms.

Cryo.s[™] and Cryo.s[™] with barcode or 2D code are defined as a specimen receptacles according to article1, para.(2)b of the IVD directive 98/79/EC and thus considered to be a 'in vitro diagnostic medical device'. **Cryo.s[™] and Cryo.s[™] with barcode or 2D code** are classified as a 'in vitro diagnostic device' according to §3, No.4, clause 2 and 3 of the directive for medicine products.

This declaration is indefinitely valid for the above mentioned products.

Frickenhausen, 22 January 2015

A. Schulz, Quality Management Director