

Declaration of Conformity
Konformitätserklärung

We

Suppliers Name

Berthold Detection Systems GmbH

Address

Bleichstrasse 56-68 D-75173 Pforzheim, Germany

declare under our sole responsibility that the product

Name, type or model

Crocodile miniWorkstation - semi automated Elisa Processor

where applicable, following the provisions of

the directive on in-vitro diagnostic medical devices 98/79/EC

classified as follows

other device (class I - device) - EDMA classification code 22 03 02 **Semi-automated I.A. Systems**

applied common technical specifications, standard(s) or other normative document(s) (if applicable)

title and/or number and date of issue of the standard(s) or other normative document(s)

Electro Magnetic Compatibility
Emission **EN 61326-2-6:2006; class B;**
Immunity **EN 61326-2-6:2006**
Safety **EN 61010-1:2002+B1:02+B2:04 and EN6101-2-101**
and other applicable standards

conformity assessment procedure

self declaration of conformity,
certified quality assurance system, according DIN EN ISO 13485:2003 + AC: 2007

Place and date of issue

10. November 2011, Pforzheim, Germany

Name and signature or equivalent marking of authorized person

Lothar Nofer, CSO

