

**EC-Conformity Declaration**  
According to the machine guideline 89/392/WEG  
Appendix II A

We, the company

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Germany

declare the analysis apparatus

Reader 220 (Pico Scan)  
OEM-Product: Milenia Biotec GmbH

manufactured by us is conform to the following guidelines:

Number of standard	Title of standard
DIN EN ISO 9001:2000	Quality management systems
DIN EN ISO 13485:2003	Quality systems – Medical devices
Directive 89/79/EG	In vitro diagnostics medical devices

As an evidence of conformity the following standards will also be fulfilled:

Number of standard	Title of standard	Version of standard
EN ISO 14971	Risk management to medical devices	2000
EN 61326+ A1 IEC 61326 + A1 DIN EN 61326 + A1	Electrical equipment for measurement, control and laboratory use; EMC requirements	1997/1998 1997/1998 1998/1999
DIN EN 61010-1	Safety regulations for electrical measurement, steering, control and laboratory instruments	2002



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