



Entra Health Systems, Ltd

Declaration of Conformity

Company : ENTRA HEALTH SYSTEMS, LTD.
Round Foundry Media Centre
Foundry Street Leeds, LS11 5QP
United Kingdom

Product : Blood Glucose Monitoring System
myglucohealth (MGH-BT1)

Classification : List B According to Annex II of IVDD
(Self testing for Blood Glucose Monitoring System)

Conformity assessment
Route : Annex IV of the IVDD
(Full QA System)

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied : See the attachment

Notified Body : TUV PRODUCT SERVICE GMBH
Ridlerstrasse 65, D-80339 Munchen, Germany

(EC) Certificate(s) : (*EC certificate(s) number(s) : V1 07 04 51015 007*)

Start of CE-marking : *27 March, 2008; Serial number of first CE Marking "809115900001"*

Place, Date of Issue : Anyang, Korea, 4th April, 2008

Signature:

John M. Hendel
Chairman
Entra Health Systems, Ltd.

	Technical File	File No.	TF01-1
		Rev. No.	0
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1.3 APPLICABLE NORMATIVE REFERENCES

1	ISO13485:2003	Quality management systems
2	Council Directive 98/79/EC	In Vitro Diagnostic Directive
3	ISO15197:2003	In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus
4	ISO15223:2002	Medical devices-Symbols to be used with medical device Labels, labeling and information to be supplied
5	ISO 14971:2003	Medical devices – Application of risk management to medical devices
6	EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control and laboratory use; General Requirements
7	IEC61010-2-101:2001	Safety requirements for electrical equipment for measurement, control and laboratory use; Particular requirements
8	IEC61000-4-2:2001	Electrostatic discharge immunity test
9	EC61000-4-3:2006	Radiated, radio-frequency, electromagnetic field immunity test
10	IEC61326:2002	Electrical equipment for measurement, control and laboratory use
11	EN60068-2-64:1994	Environmental testing
12	EN 13640:2002	Stability testing of in vitro diagnostic reagents
13	EN 376:2002	Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing
14	EN 592:2002	Instructions for use for in vitro diagnostic instruments for self-Testing
15	EN 1658:1996	Requirements for marking of in vitro diagnostic instruments
16	EN 12376:1999	Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology
17	EN 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing



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18	ISO17511:2003	Measurement of quantities in biological samples- Metrological traceability of values assigned to calibrators and control materials
19	EN 13612:2002	Performance evaluation of in vitro diagnostic reagents EN 980:1999 Graphical symbols for use in the labeling of medical devices
20	EN980:2003	Graphical symbols for use in the labeling of medical devices
21	EN12286:1999	Measurement of quantities in samples of biological origin- Presentation of reference measurement procedures
22	EN12287:1999	Measurement of quantities in samples of biological origin- Description of reference materials