

CERTIFICATE OF CONFORMITY

for Bar Code Labels

Bar code on labels for international traded medical devices shall be designed in accordance with the recognised standards of the International Standards Organisation (ISO) complying to Unique Device Identification (UDI) of the Global Harmonization Task Force (GHTF) and its supporting national institutes.

The following label was submitted for assessment and validation against the relevant ISO-standards for automatic identification by

FORESTADENT

Bernhard Förster GmbH, 75106 Pforzheim, Germany



Summary of the assessment

The label contains the Health Industry Bar Code (HIBC). The content of the symbol printed on the label conforms to "ISO 22742 Linear and 2d Bar Code for Product Packages" where HIBC, ASC or GS1 are the recognised and approved options. Chosen option is "HIBC". The Health Industry Bar Code (HIBC) label is suitable for world wide tracking and tracing and is appropriate for enabling patient safety concepts in accordance with UDI specifications of GHTF and ISO member states.

confirmed by:

*Heinrich Oehlmann
chair DIN NA 043-01-31 AA
ISO/IEC JTC 1/SC31 member*

audit assigned by:

*Dr. Tobias Weiler
Secretary EUROM MedTec*



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Date: Aug. 27, 2012

Signatures: *Heinrich Oehlmann*



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Enclosures: Technical annex and informative annex with list of ISO members

E.D.C. is accredited contributing member of ISO/IEC JTC 1/SC 31, © EDC 080201

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Technical Annex

Technical details of the product label submitted for check by

FORESTADENT
Bernhard Förster GmbH
75106 Pforzheim, Germany



The assessment verified the following parameters of the label:

- The label contains a correct Health Industry Bar Code (HIBC). The data comply with the standard “**ISO 22742** Linear and 2d Bar Code for Product Packages”, where HIBC, GS1(EAN) and ASC are the mandatory sub standards enabling unique identification and interoperability.
- The selected bar code symbology for the label is ISO/IEC 16022 **Data Matrix** according to HIBC Guidelines.
- The selected data structure is the option **HIBC** according to ISO 22742.
- The content of the primary bar code is +EFOR20409409/ carrying the data information labeller ID **EFOR**, product code **2040940**, Packaging Index **9**. The secondary part of the code \$\$810726291895O contains the data **quantity 10** and **LOT no. 26291895**.

Result of the assessment:

The Label supplied for check contains data information conforming to the ISO standard for product labelling ISO 22742 enabling Unique Device Identification (UDI).

Technically checked by:

Heinrich Oehlmann
chair DIN NA 43-01-31 AA
ISO/IEC JTC 1 SC 31 member

Eurodata Council Stichting
NL-2596 The Hague
www.Eurodatacouncil.org

Date: August 27, 2012

Signature:



Note: The assessment did not include quality measurement of the symbology according to ISO/IEC 15415/16. This is subject to testing with a bar code verifier generating a conformance grade. The Eurodata Council Stichting and committee is not responsible for consequences caused by the assessment.

Informative Annex

Excerpt of the list of ISO members and it's national standards bodies

Algeria	IANOR	Korea, Republic of	KATS
Angola	IANORQ	Kuwait	KOWSMD
Argentina	IRAM	Lebanon	LIBNOR
Australia	SA	Libyan Arab Jamahiriya	LNCSM
Austria	ON	Luxembourg	SEE
Bahrain	BSMD	Malaysia	DSM
Bangladesh	BSTI	Mexico	DGN
Belarus	BELST	Morocco	SNIMA
Belgium	NBN	Netherlands	NEN
Bosnia Herzegovina	BAS	Norway	SN
Botswana	BOBS	Oman	DGSM
Brazil	ABNT	Pakistan	PSQCA
Bulgaria	BDS	Peru	INDECOPI
Canada	SCC	Philippines	BPS
Chile	INN	Poland	PKN
China	SAC	Portugal	IPQ
Congo	OCC	Romania	ASRO
Cuba	NC	Russian Federation	GOST R
Croatia	HZN	Saudi Arabia	SASO
Cuba	NC	Serbia	ISS
Czech Republic	CNI	Singapore	SPRING SG
Denmark	DS	Slovakia	SUTN
Egypt	EOS	Slovenia	SIST
Ethiopia	QSAE	South Africa	SABS
Finland	SFS	Spain	AENOR
France	AFNOR	Sudan	SSMO
Ghana	GSB	Sweden	SIS
Germany	DIN	Switzerland	SNV
Greece	ELOT	Syrian Arab Republic	SASMO
Hungary	MSZT	Tanzania	TBS
India	BIS	Thailand	TISI
Indonesia	BSN	Tunisia	INNORPI
Iran	ISIRI	Turkey	TSE
Iraq	COSQC	USA	ANSI
Ireland	NSAI	Uganda	UNBS
Israel	SII	Ukraine	DSSU
Italy	UNI	United Arab Emirates	ESMA
Japan	JISC	United Kingdom	BSI
Jordan	JISM	Uruguay	UNIT
Kenya	KEBS	Viet Nam	TCVN
Korea D. P. R.	CSK		

Note: Complete list with updates see source www.iso.org/iso/iso_members

Source of ISO standards: National standardisation bodies listed above or www.ISO.org