HIBC solution for EU MDR/IVDR Basic UDI-DI

European Medical Device regulation (1) and In-Vitro Diagnostica regulation (2) defines the Basic UDI-DI for the Eudamed Data Base and for the Certificates issued by Notified Bodies.

The Basic UDI-DI is constructed by the device manufacturer following the rules of the accredited issuing agencies. This document is describing the construction rules for Basic UDI-DI of the issuing agency for HIBC.

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1. Content

2. What is a basic UDI-DI?

THe Basic UDI-DI is grouping a set of physical devices/packages and establishes a link to the relevant certificate issued by the notified body. Thus, It is defined for use in the Eudamed database and on device certificates issued by notified bodies.

The Basic UDI-DI is assigned by the device manufacturer following the rules of issuing entities.

The manufacturer creates one descriptive device record per Basic UDI-DI in the Eudamed Device UDI module.

Each physical device has a UDI on its label, which is referencing to a Basic UDI-DI within its record in the Eudamed UDI module. Each entry in the UDI module of Eudamed references one Basic UDI-DI.

The Basic UDI-DI is not printed on the device label.

3. HIBC rules for Basic UDI-DI

3.1. Structure

Basic UDI-DI values are created by the LIC-holder. The Basic UDI-DI consists of the following fields being concatenated:

Abreviation	Name	Format	Example	Description
IAC	Issuing Agency Code	0..3 alphanumerics	RH	Issuing agency code for the issuer as defined by . ISO/IEC 15459 (3). The list of codes may be downloaded at AIM Global (4).
LIC	Labeler Issuer Code	1 alpha + 3 alphanumeric	E999	Labeler Issuer Code. This unique labeler identification code is assigned by the issuing agency.
BDN	Basic UDI-DI Device Number	1 to 20 alphanumerics plus special characters "-.,:;"§$%&()=?+#<>" The HIBC field separator "/" and space " " is explicitly omitted.	AQ7B5	Basic UDI-DI issued uniquely by the LIC-holder.

3.2. Uniqueness to Basic UDI-DI issued by other issuing entities

The Issuing agency code is used as a prefix to get world unique codes issued by different issuing agencies.

The definition of the GS1 Global Model Number GMN (5) is following this rule, as the GS1 issuing agency code is 0 to 9.

3.3. Uniqueness of Basic UDI-DI and UDI-DI

Basic UDI-DI and UDI-DI should not overlap.

This condition is fulfilled if no LIC code starts with "RH". This is the case as those codes are not issued.

3.4. Basic UDI-DI Device Number

Each manufacturer may use the BDN field to create a Basic UDI-DI according his numbering scheme.

There are no rules implied of the construction of this field other than the character set of the BDN.

Nevertheless, the following strategies may be considered on a company level:

- Choose the Basic UDI-DI Device Number field as the certificate number plus a number to identify the device covered by the certificate.
- Choose the Basic UDI-DI equal to the UDI-DI PCN field, if there is a 1:1 relationship (6).
- Choose a device document number from the life-cycle management system of the manufacturer, which is unique within the companies domain.

The upper possibilities may be used as a mixed setup as long as uniqueness is maintained.

3.5. Example

The example values given in the upper table result in the final Basic UDI-DI value:

RHE999AQ7B5

This number is constructed by the concatenation of the fields IAC, LIC and BDN.

4. Literature

1. **European_Union.** EU Medical Device Regulation 2017/745. [Online] 2017. http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=OJ%3AL%3A2017%3A117%3ATOC.

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4. **Global, AIM.** Registration Authority - ISO / IEC 15459. [Online] 2017. http://www.aimglobal.org/?Reg_Authority15459.

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