DG Growth

Management of Legacy Devices

MDR Eudamed

Date: 30.07.2019

Doc. Version: 1.1

Table of Contents

1 Introduction

This document contains the details of how Legacy Devices will be identified in EUDAMED and the way the different unique Device identifiers for the Legacy Devices will be generated/assigned.

2 General Considerations

Legacy Devices are defined as Medical Devices, Active Implantable Medical Devices and In Vitro Diagnostic Medical Devices that are covered by a valid certificate issued in accordance with Directive 93/42/EEC or Directive 90/385/EEC or Directive 98/79/EC and that continues to be placed on the market after the date of application of Regulation (EU) 2017/745 (MDR) or Regulation 2017/746 (IVDR).

Guidance on registration of legacy devices in Eudamed is provided in the "MDCG 2019-5 Registration of legacy devices in EUDAMED April 2019 " document (https://ec.europa.eu/docsroom/documents/34922).

Manufacturers will have the possibility to register in EUDAMED any of their Legacy Devices.
As explained in the guidance document, their registration in Eudamed will be mandatory in case there is a serious incident that occurs or a field safety corrective action to apply on them, requiring then their registration as soon as possible and at least before a follow up or final vigilance report is submitted.
Furthermore, if 18 months after the date of application of the MDR or IVDR (or 24 months after the date of publication of the notice referred to in Article 34(3) if Eudamed is not available with the functionality before date of application of MDR) the equivalent device is not made compliant and registered as a MDR or IVDR device, the legacy device will have to be registered in Eudamed within the 18 months after date of application (or 24 months after the date of publication of the notice referred to in Article 34(3)).

The Directives Devices with the Risk Class I that are not sterile and/or with a measuring function under the Directives cannot be considered as Legacy Devices because not requiring a certificate issued by a Notified Body. Those will have to be registered in Eudamed only as Regulation Devices within the 18 months after date of application (or 24 months after the date of publication of the notice referred to in Article 34(3) if Eudamed is not available with the functionality before date of application of MDR).

3 Identification details for Legacy Devices

Legacy Devices are subject to the MDR or IVDR registration requirements with some exceptions such as the assignation of a Basic UDI-DI and a UDI-DI.

Even if the Basic UDI-DI and UDI-DI are not required to be assigned for a Legacy Device, in order to keep the same standard structure and identification elements for all Devices registered in EUDAMED, identification elements: EUDAMED DI, equivalent of the Basic UDI-DI, will be required and EUDAMED ID in case no UDI-DI has been assigned will be generated from EUDAMED DI for Legacy Devices.

Therefore, Basic UDI-DI will never be applicable and never to be assigned to a Legacy Device but only EUDAMED DI, where on the other hand, a UDI-DI can be used to identify a Legacy Device in Eudamed.

Moreover, only one device identifier will have to be assigned to a Legacy Device, either a UDI-DI (the EUDAMED DI being then automatically generated from UDI-DI) or a EUDAMED DI (the EUDAMED ID being then automatically generated from the EUDAMED DI).

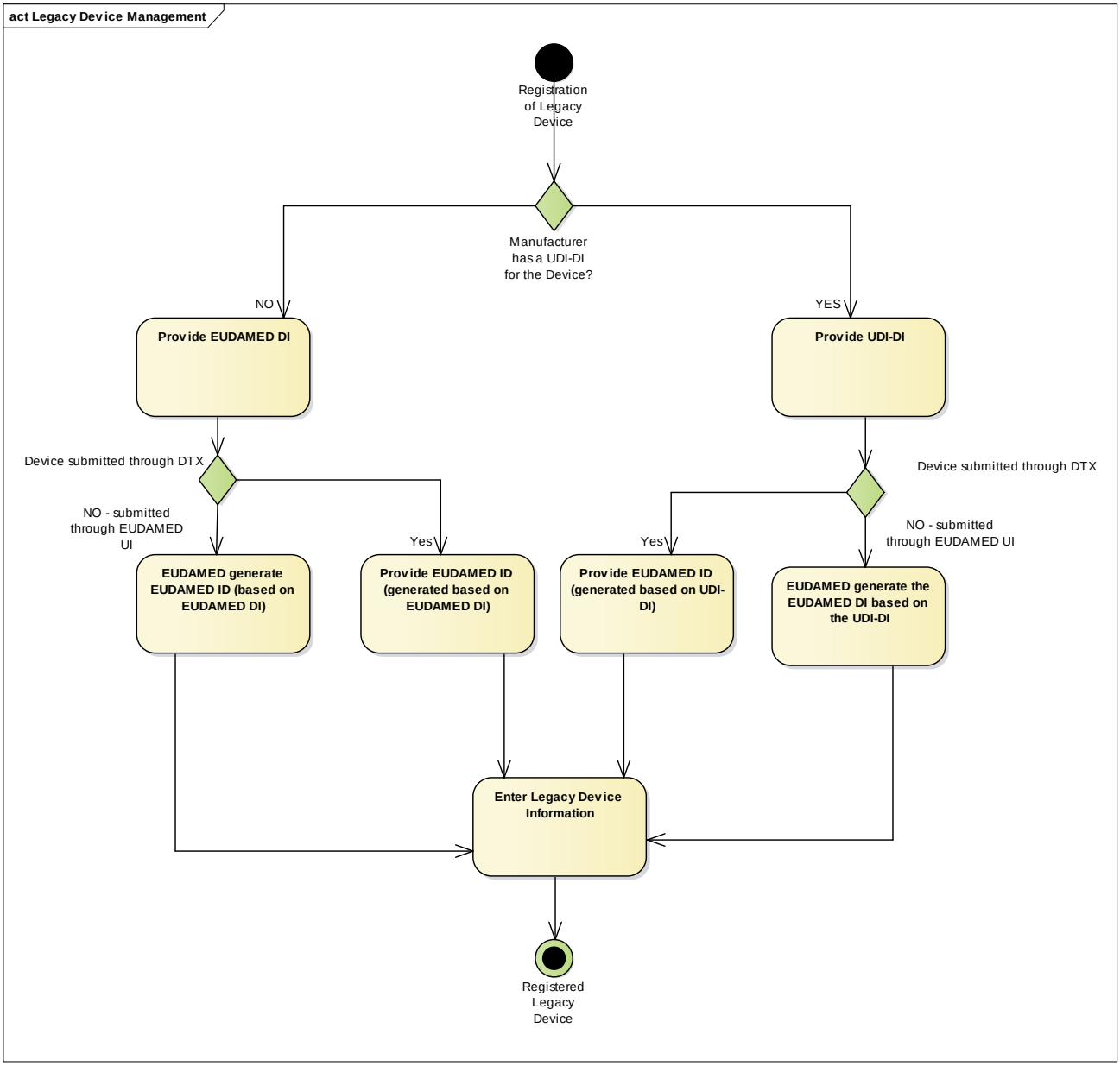

Figure 1 - Management of Device unique identification elements for Legacy Devices

Case 1 : Generation of identification details for a Legacy Device when a UDI-DI already exists

In case the Manufacturer has already a UDI-DI assigned to a Legacy Device, he will be able to use this UDI-DI as device identifier in Eudamed for the Legacy Device. In this case, the UDI-DI will be provided with the Device data element as a unique device identifier in Eudamed, and the EUDAMED DI can be automatically generated from the UDI-DI value.

The Legacy Device will have in this case, the following identification elements: a EUDAMED DI (generated based on the UDI-DI) and a UDI-DI (assigned by the Manufacturer).

In order to generate the EUDAMED DI identification element from the UDI-DI provided, EUDAMED will use a standard format, placing the characters "***B-***" in front of the UDI-DI provided

Example:
Provided UDI-DI***: M991CVS12130NES2***
Generated EUDAMED DI***: B-M991CVS12130NES2***

Case 2 : Generation of identification details for a Legacy Device when a UDI-DI does not exist

In case the Manufacturer does not have a UDI-DI assigned for a Legacy Device, Manufacturer will have to assign a EUDAMED DI and EUDAMED ID.

EUDAMED DI will have a strict format, starting with 'B-' as a prefix and continuing with a set of characters – as defined in Annex 1.

EUDAMED ID will have the same format and value as EUDAMED DI except the first prefix character. It will start with 'D' instead of 'B'.

Example:
EUDAMED DI ***:*** **B-BEMF000000106CR023335MS**
EUDAMED ID ***:*** **D-BEMF000000106CR023335MS**

4 Linking the Regulation Devices to Legacy Devices

When the equivalent of a Legacy Device becomes Regulation Device compliant (having fulfilled all MDR or IVDR requirements like to be covered by the required MDR or IVDR certificate(s)), a new Regulation Device shall be registered in EUDAMED in accordance with the MDR/IVDR requirements.
EUDAMED will allow the linking of the Regulation Device with the Legacy Device and it will perform this linking automatically where the same UDI-DI has been assigned to both the Legacy Device and the Regulation Device. The link will be made at the level of the UDI-DI.

If the Regulation Device is exactly the same as the Legacy Device except that its is MDR or IVDR compliant, the Regulation Device may have the same UDI-DI as the Legacy Device and in this case, the link between the two devices will be made automatically, otherwise the link can be created manually by the Manufacturer by providing the Legacy Device device identifier.

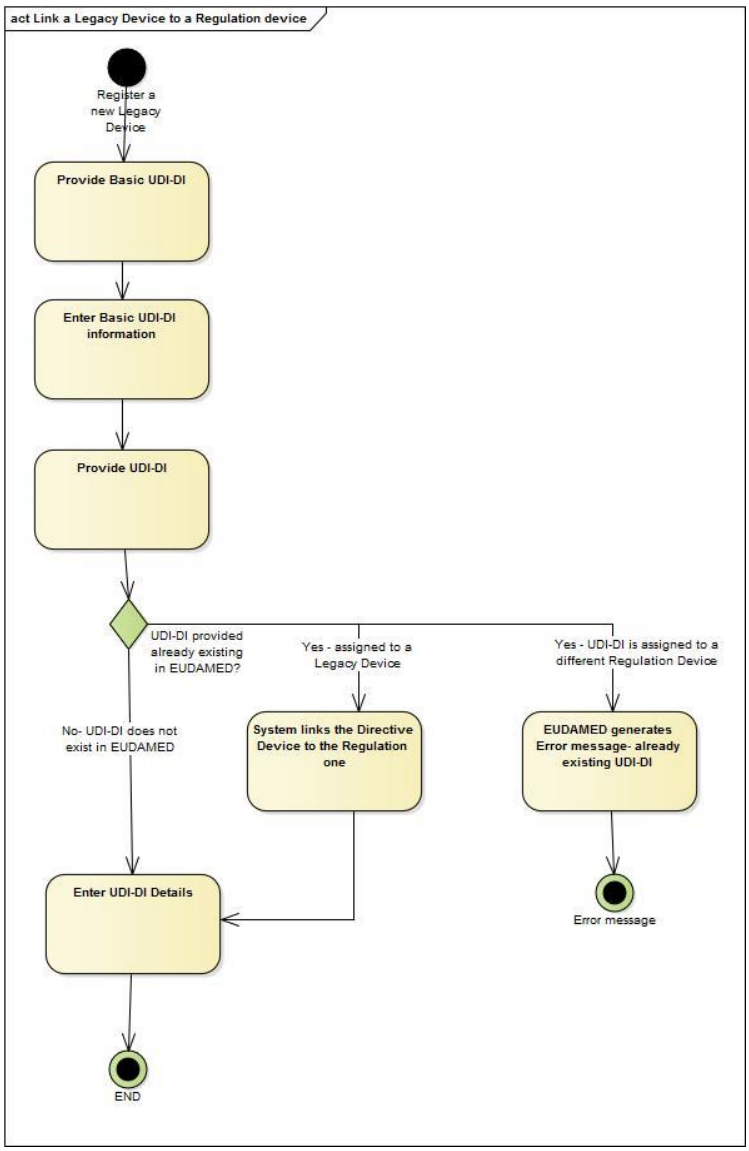

Figure 2 - Registration of Regulation Device

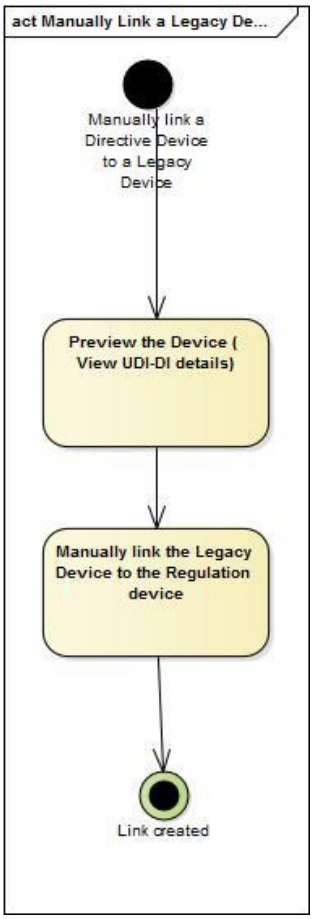

Figure 3 - Manual Linking of Legacy Device to a Regulation Device

Annex 1 : Format of the EUDAMED DI identification number (when not generated from UDI-DI)

In order to keep a consistency in the formatting structure of the EUDAMED DI and the Basic UDI-DI structures used by Issuing Entities, EUDAMED is proposing a structure similar to the Global Model Number (GMN).

Key characteristics of the format structure:

- 25 characters maximum length of the identifier (including the prefix and check digits);
- allows the use of characters inside the code - permits the use of a subset of characters already implemented in other formatting structures by different other entities;
- implements a two key check-digit;
- Prefix (B-) implemented in order to create a easily recognisable format for EUDAMED DI

Note: Due to the fact that the format for generating the EUDAMED DI codes would not include necessarily the unique identification number of the Manufacturer provided by EUDAMED (Manufacturer SRN), there is a risk that the same code is assigned by two different Manufacturer`s for different Devices.

> **As best practice, Manufacturer SRN should be used in the unique identifier assigned by the Manufacturer (described in the section Format for EUDAMED DI code) for the generation of EUDAMED DI.**

In order to prevent duplicates to be registered an uniqueness check is implemented in EUDAMED - EUDAMED DI together with the Issuing Entity (EUDAMED DI and EUDAMED ID will have by default the issuing entity "EUDAMED") are checked for uniqueness. In case a manufacturer has already registered a Legacy Device in Eudamed with a EUDAMED DI code, any other Legacy Device to which the same EUDAMED DI code would have been assigned will be refused by Eudamed for registration.

Format of the EUDAMED DI code

EUDAMED DI Format		
Prefix	Manufacturer`s unique reference	Check Characters
B -	C1.....Cn (n<=21)	Cn+1 Cn+2

B-' - Prefix defined for EUDAMED DI (required by default) - not taken into account into the Check-digit calculation

C - characters used in the Code generation

C1-Cn - Unique identifier assigned by the Manufacturer for the Device. Cannot go above 21. Optionally can include in the beginning the SRN of the Manufacturer (without the '-' characters) : C1...C13;

Cn+1 and Cn+2 - Check Digit characters;

Calculation Steps

Step 1: Assigning a reference value

For each character inside the Code, except the first 2 characters composing the prefix ('B-'), identify the assigned value in Table 1 – Reference value;

Step 2: Assigning a prime number weight for each element

Assign a prime number weight – starting with the right most non-check character and continuing until the first character in the Code;

Step 3: Determine the total value

Multiply the Reference value assigned at Step 1 and the weight assigned in Step 2 for each character apart and make a total of the values obtained;

Step 4: Apply Modulo 1021 to the total value obtained

Perform MOD (1021) operation on the sum obtained at Step 4. Value obtained will be used for further calculations of the Check-digit number – Ck.

Ck= Mod (1021) Total Value (value of Step 3);

Step 5: Determine the value of the first Check-digit

The Assigned value for the first Check-Digit is obtained by obtaining the integer value of the Check-digit number(value Step 4) split by 32: Assigned v*alue= Int(Ck / 32)*;

The Assigned value obtained will be used in Table 2 in order to obtain the corresponding Character set for Check-Digit C(n+1);

Step 6: Determine the value of the second Check-digit

The Assigned value for the second Check-Digit is obtained by applying Modulo 32 to the Check-digit number (value Step 4) : Assigned value = Mod(32)Ck;

The Assigned value obtained will be used in Table 2 in order to obtain the corresponding Character set for Check-Digit C(n+2);

Reference Table 1 – Reference values for the characters used in the Code

Character set	Assigned Value
!	0
"	1
%	2
&	3
'	4
(	5
)	6
*	7
+	8
,	9
-	10
.	11
/	12
0	13
1	14
2	15
3	16
4	17
5	18
6	19
7	20
8	21
9	22
:	23
;	24
<	25
=	26
>	27
?	28
A	29

Character set	Assigned Value
B	30
C	31
D	32
E	33
F	34
G	35
H	36
I	37
J	38
K	39
L	40
M	41
N	42
O	43
P	44
Q	45
R	46
S	47
T	48
U	49
V	50
W	51
X	52
Y	53
Z	54
_	55
a	56
b	57
c	58
d	59

Character set	Assigned Value
e	60
f	61
g	62
h	63
i	64
j	65
k	66
l	67
m	68
n	69
o	70
p	71
q	72
r	73
s	74
t	75
u	76
v	77
w	78
x	79
y	80
z	81

Reference Table 2 – Reference value for Check-digit calculations

Character set	Assigned Value
2	0
3	1
4	2
5	3
6	4
7	5
8	6
9	7
A	8
C	9
D	10

Character set	Assigned Value
E	11
F	12
G	13
H	14
I	15
J	16
K	17
L	18
M	19
N	20
P	21

Character set	Assigned Value
Q	22
R	23
S	24
T	25
U	26
V	27
W	28
X	29
Y	30
Z	31

Calculation examples

Example 1

Manufacturer SRN: **BE– MF-000000106**

Note: Providing the SRN is optional, but is recommended. If providing the SRN Code the separation '-' characters shall not be included from the SRN (in order to optimise the number of characters available for the manufacturer to assign a Device identifier);

Manufacturer Code provided for the product: **CR023335**
EUDAMED DI: **B-BEMF000000106CR023335MS**
EUDAMED ID: **D-BEMF000000106CR023335MS**

EUDAMED DI generation

	Prefix		Unique ID Provided by the Manufacturer																				Check-Digit	
	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	C18	C19	C20	C21	C22	C23	C24	C25
	B	-	B	E	M	F	0	0	0	0	0	0	1	0	6	C	R	0	2	3	3	3	5	M	S
Assigned reference Value (according Table 1)			30	33	41	34	13	13	13	13	13	13	14	13	19	31	46	13	15	16	16	16	18		
Assigned weight			73	71	67	61	59	53	47	43	41	37	31	29	23	19	17	13	11	7	5	3	2		
Total (Assigned Reference Value and Assigned weight)			2190	2343	2747	2074	767	689	611	559	533	481	434	377	437	589	782	169	165	112	80	48	36		

Total value	16223	
CK (Mod (Total Value); (1021))	908	
Assigned Value (C24) = Integer value of (CK / 32)	19	**Corresponding Character (Table 2) = M**
Assigned value (C25) = Mod(CK; 32)	24	**Corresponding Character (Table 2) = S**

Example 2

Manufacturer Code provided for the product: **CR0233**
EUDAMED DI: **B-CR023368**
EUDAMED ID: **D-CR023368**

EUDAMED DI generation

	Prefix		Unique ID Provided by the Manufacturer						Check-Digit	
	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10
	B	-	C	R	0	2	3	3	6	8
Assigned reference Value (according Table 1)			31	46	13	15	16	16		
Assigned weight			13	11	7	5	3	2		
Total (Assigned Reference Value and Assigned weight)			403	506	91	75	48	32		

Total value	1155	
CK (Mod (Total Value); (1021))	134	
Assigned Value (C9) = Integer value of (CK / 32)	4	**Corresponding Character (Table 2) = 6**
Assigned value (C10) = Mod(CK; 32)	6	**Corresponding Character (Table 2) = 8**