

UDI/Device - Enumerations - 2.7

1 - Introduction

This "Enumerations" document contains the value lists for drop down elements and lists where a limited set of values can be selected.

2 - Purpose

This purpose of this document is to provide an overview of the possible values fields can contain to be valid information for EUDAMED.

3 - Scope

We opted to provide enumerations and their detailed descriptions by module. This document refers to UDI/Device module Enumerations only.

4 - Changelog

Changed

- Update of Measure Unit enumeration - [BR-UDID-800 : Clinical Size Measure Unit - ENUM_UDID_ClinicalSizeMeasureUnit](#)

(Standard MU - changed code to MU176)

- Update of Enumeration for Special Device types (split by Applicable Legislation) - [BR-UDID-818 : Special Device Type - ENUM_UDID_SpecialDevice](#)

4 - Enumerations

Summary	Updated	Status	Description
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For MDR certificates (see) the certificate type can be:

Label	Value	Sort order
(MDR) EU Quality Management System certificate (Annex IX Chapter I)	MDR_QUALITY_MANAGEMENT_SYSTEM	1
(MDR) EU Technical Documentation certificate (Annex IX Chapter II)	MDR_TECHNICAL_DOCUMENTATION	2
(MDR) EU Type Examination certificate (Annex X)	MDR_TYPE_EXAMINATION	3
(MDR) EU Quality Assurance certificate (Annex XI Part A)	MDR_QUALITY_ASSURANCE	4
(MDR) EU Product verification certificate (Annex XI Part B)	MDR_PRODUCT_VERIFICATION	5

For IVDR certificates (see) the certificate type can be:

Label	Value	Sort order
(IVDR) EU Quality Management System certificate (Annex IX Chapter I)	IVDR_QUALITY_MANAGEMENT_SYSTEM	1
(IVDR) EU Technical Documentation certificate (Annex IX Chapter II)	IVDR_TECHNICAL_DOCUMENTATION	2
(IVDR) EU Type Examination certificate (Annex X)	IVDR_TYPE_EXAMINATION	3
(IVDR) EU Production Quality Assurance certificate (Annex XI)	IVDR_PRODUCTION_QUALITY_ASSURANCE	4

Applicable Legislation valid for a Regulation Device are :

Label	Value	Notes
REGULATION (EU) 2017/745 on medical devices	MDR	
REGULATION (EU) 2017/746 on in vitro diagnostic medical devices	IVDR	

Applicable Legislation valid for a Legacy Device are:

Label	Value	Notes
Council Directive 93/42/EEC on Medical devices	MDD	
Council Directive 90/385/EEC - Approximation of the laws of the Member States relating to active implantable medical devices	AIMDD	
Directive 98/79/EC on in vitro diagnostic medical devices	IVDD	

Applicable Legislation valid for a System or Procedure Pack :

Label	Value	Notes
REGULATION (EU) 2017/745 on medical devices	MDR	

Name	Code
%	MU01
/litre (L)	MU02
/millilitre (mL)	MU03
/millimole (mmol)	MU04
Active	MU138
Adult	MU168
ampere (A)	MU107
Angled	MU140
atomic mass unit: u	MU87
atomic mass unit: u per 12h	MU89
atomic mass unit: u per 1h	MU88
atomic mass unit: u per 2h	MU90
atomic mass unit: u per d	MU91
atomic mass unit: u per g	MU92
atomic mass unit: u per kg	MU93
atomic mass unit: u per mL	MU94
bar (bar)	MU126
becquerel (Bq)	MU122
bel (B)	MU133
Belt	MU154
candela (cd)	MU109
centilitre (cL)	MU09
centimetre (cm)	MU10
centimetre per second (cm/s)	MU11
Child	MU167
Concave	MU158
Contour	MU151
Convex	MU156
Convex light	MU157
coulomb (C)	MU113
cubic centimetre (cu cm or cm ³)	MU12
cubic millimetre (cu mm or mm ³)	MU13
cup	MU14
Curved	MU175
dalton (Da)	MU131
day (d)	MU15
decibel (dB)	MU134
decilitre (dL)	MU16
decimetre (dm)	MU17
degree (°)	MU105
degree Celsius (°C)	MU18
dioptr (D)	MU104
electronvolt (eV)	MU127
Extra large (XL)	MU164

Extra small (XS)	MU160
farad (F)	MU117
femtolitre (fL)	MU21
femtometre (fm)	MU20
femtomole/litre (fmol/L)	MU22
Flat	MU159
foot (ft)	MU23
French (F)	MU170
gram (g)	MU24
gram per litre (g/L)	MU25
gray (Gy)	MU123
hectare (ha)	MU129
Heel	MU150
henry (H)	MU120
hertz (Hz)	MU27
hour (h)	MU26
inch (in)	MU28
Infant	MU166
international unit [IU]	MU05
international unit per day [IU]/day ([IU]/d)	MU06
international unit per litre [IU]/litre [IU]/L	MU07
international unit per millilitre [IU]/millilitre [IU]/mL	MU08
joule (J)	MU112
J-tip	MU141
katal (kat)	MU125
kelvin (K)	MU108
kilogram (kg)	MU29
kilolitre (KL)	MU30
kilometre (km)	MU31
kilopascal (kPa)	MU32
kiloU per litre (kU/L)	MU33
Large (L)	MU163
left	MU172
litre (L)	MU34
lumen (lm)	MU106
lux (lx)	MU121
Medium (M)	MU162
metre (m)	MU36
micro[iU] per millilitre (μ [iU]/mL or μ [iU]/ml)	MU95
microgram (μ g)	MU40
microgram per day (μ g/d)	MU96
microgram per decilitre μ g/dL	MU135
microgram per litre (μ g/L)	MU97
microgram per millilitre (μ g/mL)	MU98
microgram per minute (μ g/min)	MU41

microlitre (μL or μl)	MU42
micrometre (μm)	MU43
micrometre per second ($\mu\text{m/s}$)	MU99
micromole (μmol)	MU44
micromole per gram ($\mu\text{mol/g}$)	MU100
micromole per litre ($\mu\text{mol/L}$)	MU45
micromoles per minute (=1 mol/min)	MU19
milli international unit per litre (m[iU]/L)	MU35
millibar (mbar)	MU46
milliequivalent (mEq)	MU47
milligram (mg)	MU37
milligram per decilitre (mg/dL)	MU136
milligram per litre (mg/L)	MU38
milligram per millilitre (mg/mL)	MU39
millilitre (mL)	MU48
millilitre per day (mL/d)	MU56
millilitre per minute (mL or ml/min)	MU57
millilitre per second (mL/s)	MU49
millimetre (mm)	MU50
millimetre of mercury (mm Hg)	MU51
millimetre per hour (mm/h)	MU58
millimole (mmol)	MU52
millimole per gram (mmol/g)	MU59
millimole per kilogram (mmol/kg)	MU60
millimole per kilogram[H ₂ O] (mmol/kg[H ₂ O])	MU61
millimoles per litre (mmol/L)	MU53
millisecond (ms)	MU54
Mini	MU147
minute (min)	MU55
mole (mol)	MU62
month	MU63
Multishape	MU149
nanogram (ng)	MU64
nanogram per litre (ng/L)	MU67
nanogram per millilitre (ng/mL)	MU68
nanolitre (nL)	MU65
nanometre (nm)	MU66
nanomole per day (nmol/d)	MU69
nanomole per gram (nmol/g)	MU70
nanomole per hour per millilitre (nmol/h/mL or nmol/h/ml)	MU71
nanomole per litre (nmol/L)	MU72
Neonate	MU165
neper (Np)	MU132
newton (N)	MU110
ohm (Ω)	MU115

pascal (Pa)	MU111
Passive	MU137
pH (pH)	MU169
picogram (pg)	MU73
picogram per millilitre (pg/mL)	MU74
picolitre (pL)	MU75
picometre (pm)	MU76
picomole per gram (pmol/g)	MU77
picomole per hour per milligram (pmol/h/mg)	MU78
picomole per hour per millilitre (pmol/h/mL or pmol/h/ml)	MU79
picomole per litre (pmol/L)	MU80
Rectangular	MU153
right	MU173
Sacral	MU148
second (s)	MU81
siemens (S)	MU116
sievert (Sv)	MU124
Small (S)	MU161
Soft angled	MU144
Soft straight	MU142
Square	MU152
square centimetre (sq cm or cm ²)	MU82
square foot (sq ft)	MU83
square inch (sq in)	MU84
square metre (sq m or m ²)	MU85
square millimetre (sq mm or mm ²)	MU86
Standard	MU176
Stiff angled	MU145
Stiff J-tip	MU146
Stiff straight	MU143
Straight	MU139
tesla (T)	MU119
tonne (metric ton)	MU130
unified atomic mass unit (u)	MU128
volt (V)	MU114
watt (W)	MU103
weber (Wb)	MU118
week	MU101
year	MU102
OTHER	MU999

BR-UDID-801 : Clinical Size Precision -
ENUM_UDID_ClinicalSizePrecision

Sep 27,
2021

RESOLVED

Label	Value	Notes	Sort Order
Value	Value		1
Text	Text		2
Range	Range		3

BR-UDID-802 : Clinical Size Type -
ENUM_UDID_ClinicalSizeType

Sep 27,
2021

RESOLVED

Name	Code
Acidity	CST1
Amount of fingers	CST2
Angle	CST3
Bevel	CST4
Concentration	CST5
Cannula wall	CST6
Capacity	CST7
Coating	CST8
Diameter	CST9
Diameter (inner)	CST10
Diameter (outer)	CST11
Pole distance	CST12
Flow rate	CST13
Gauge	CST14
Guide wire type	CST15
Inflation volume	CST16
Body side	CST17
Balloon length (nominal)	CST18
Length	CST19
Luminous flux	CST20
Particle size	CST21
Nominal capacity	CST22
Number of electrodes	CST23
Pore size	CST24
Pressure	CST25
Shape/form	CST26
Size	CST27
Stiffness	CST28
Strength	CST29
Surface area	CST30
Tip fixation/anchoring	CST31
Volume	CST32
Width	CST33
Weight	CST34
Type of patient	CST35

Wavelength	CST36
Frequency	CST37
Optical power	CST38
Cylinder power	CST39
Addition power (Optical)	CST40
Cylinder axis	CST41
Base curve (B.C. or R0)	CST42
Optical zone diameter	CST43
Power profile (optical)	CST44
Colour	CST45
Edge lift	CST46
Prism	CST47
Cel	CST48
Radius	CST49
Tangent	CST50
Height	CST51
Centre thickness	CST52
Truncation	CST53
Truncation axis	CST54
Edge radius	CST55
Body weight [kg]	CST56
Back cylinder power	CST57
Back cylinder axis	CST58
Optical zone diameter back	CST59
Prism axis	CST60
Tangent steep	CST61
Height steep	CST62
Direction of view	CST63
OTHER	CST999
Circumference	CST65
Depth	CST66
Enzyme catalytic activity	CST67

BR-UDID-803 : CMR Type -
ENUM_UDID_CMRTYPE

Sep 27,
2021

RESOLVED

Label	Value	Notes	Sort Order
1A	CMR_1A		1
1B	CMR_1B		2

Label	Value	Notes	Sort Order
On the market	ON_THE_MARKET		1
No longer placed on the market	NO_LONGER_PLACED_ON_THE_MARKET		2

Label	Value	Notes
P307 – IF exposed: P312 – Call a POISON CENTER or doctor /physician if you feel unwell.	CW301	
P308 – IF exposed or concerned: P312 – Call a POISON CENTER or doctor/physician if you feel unwell.	CW302	
P309 – IF exposed or if you feel unwell: P312 – Call a POISON CENTER or doctor/physician if you feel unwell.	CW303	
P337 – If eye irritation persists: P313 – Get medical advice /attention.	CW304	
P332 – If skin irritation occurs: P313 – Get medical advice /attention.	CW305	
P333 – If skin irritation or rash occurs: P313 – Get medical advice/attention.	CW306	
P301 – IF SWALLOWED: P313 – Get medical advice/attention.	CW307	
P302 – IF ON SKIN: P313 – Get medical advice/attention.	CW308	
P303 – IF ON SKIN (or hair): P313 – Get medical advice /attention.	CW309	
P304 – IF INHALED: P313 – Get medical advice/attention.	CW310	
P305 – IF IN EYES: P313 – Get medical advice/attention.	CW311	
P307 – IF exposed: P313 – Get medical advice/attention.	CW312	
P308 – IF exposed or concerned: P313 – Get medical advice /attention.	CW313	

P309 – IF exposed or if you feel unwell: P313 – Get medical advice/attention.	C W 3 14
P337 – If eye irritation persists: P314 – Get medical advice /attention if you feel unwell.	C W 3 15
P332 – If skin irritation occurs: P314 – Get medical advice /attention if you feel unwell.	C W 3 16
P333 – If skin irritation or rash occurs: P314 – Get medical advice/attention if you feel unwell.	C W 3 17
P301 – IF SWALLOWED: P314 – Get medical advice/attention if you feel unwell.	C W 3 18
P302 – IF ON SKIN: P314 – Get medical advice/attention if you feel unwell.	C W 3 19
P303 – IF ON SKIN (or hair): P314 – Get medical advice /attention if you feel unwell.	C W 3 20
P304 – IF INHALED: P314 – Get medical advice/attention if you feel unwell.	C W 3 21
P305 – IF IN EYES: P314 – Get medical advice/attention if you feel unwell.	C W 3 22
P306 – IF ON CLOTHING: P314 – Get medical advice/attention if you feel unwell.	C W 3 23
P307 – IF exposed: P314 – Get medical advice/attention if you feel unwell.	C W 3 24
P308 – IF exposed or concerned: P314 – Get medical advice /attention if you feel unwell.	C W 3 25
P309 – IF exposed or if you feel unwell: P314 – Get medical advice/attention if you feel unwell.	C W 3 26
P337 – If eye irritation persists: P315 – Get immediate medical advice/attention.	C W 3 27
P332 – If skin irritation occurs: P315 – Get immediate medical advice/attention.	C W 3 28
P333 – If skin irritation or rash occurs: P315 – Get immediate medical advice/attention.	C W 3 29
P301 – IF SWALLOWED: P315 – Get immediate medical advice /attention.	C W 3 30

P302 – IF ON SKIN: P315 – Get immediate medical advice /attention.	C W 3 31
P303 – IF ON SKIN (or hair): P315 – Get immediate medical advice/attention.	C W 3 32
P304 – IF INHALED: P315 – Get immediate medical advice /attention.	C W 3 33
P305 – IF IN EYES: P315 – Get immediate medical advice /attention.	C W 3 34
P307 – IF exposed: P315 – Get immediate medical advice /attention.	C W 3 35
P308 – IF exposed or concerned: P315 – Get immediate medical advice/attention.	C W 3 36
P309 – IF exposed or if you feel unwell: P315 – Get immediate medical advice/attention.	C W 3 37
P337 – If eye irritation persists: P320 – Specific treatment is urgent (see on this label).	C W 3 38
P332 – If skin irritation occurs: P320 – Specific treatment is urgent (see on this label).	C W 3 39
P333 – If skin irritation or rash occurs: P320 – Specific treatment is urgent (see on this label).	C W 3 40
P301 – IF SWALLOWED: P320 – Specific treatment is urgent (see on this label).	C W 3 41
P302 – IF ON SKIN: P320 – Specific treatment is urgent (see on this label).	C W 3 42
P303 – IF ON SKIN (or hair): P320 – Specific treatment is urgent (see on this label).	C W 3 43
P304 – IF INHALED: P320 – Specific treatment is urgent (see on this label).	C W 3 44
P305 – IF IN EYES: P320 – Specific treatment is urgent (see on this label).	C W 3 45
P306 – IF ON CLOTHING: P320 – Specific treatment is urgent (see on this label).	C W 3 46
P307 – IF exposed: P320 – Specific treatment is urgent (see on this label).	C W 3 47

P308 – IF exposed or concerned: P320 – Specific treatment is urgent (see on this label).	C W 3 48
P309 – IF exposed or if you feel unwell: P320 – Specific treatment is urgent (see on this label).	C W 3 49
P337 – If eye irritation persists: P321 – Specific treatment (see on this label).	C W 3 50
P332 – If skin irritation occurs: P321 – Specific treatment (see on this label).	C W 3 51
P333 – If skin irritation or rash occurs: P321 – Specific treatment (see on this label).	C W 3 52
P301 – IF SWALLOWED: P321 – Specific treatment (see on this label).	C W 3 53
P302 – IF ON SKIN: P321 – Specific treatment (see on this label).	C W 3 54
P303 – IF ON SKIN (or hair): P321 – Specific treatment (see on this label).	C W 3 55
P304 – IF INHALED: P321 – Specific treatment (see on this label).	C W 3 56
P305 – IF IN EYES: P321 – Specific treatment (see on this label).	C W 3 57
P306 – IF ON CLOTHING: P321 – Specific treatment (see on this label).	C W 3 58
P307 – IF exposed: P321 – Specific treatment (see on this label).	C W 3 59
P308 – IF exposed or concerned: P321 – Specific treatment (see on this label).	C W 3 60
P309 – IF exposed or if you feel unwell: P321 – Specific treatment (see on this label).	C W 3 61
P337 – If eye irritation persists: P322 – Specific measures (see on this label).	C W 3 62
P301 – IF SWALLOWED: P322 – Specific measures (see on this label).	C W 3 63
P302 – IF ON SKIN: P322 – Specific measures (see on this label).	C W 3 64

P303 – IF ON SKIN (or hair): P322 – Specific measures (see on this label).	C W 3 65
P304 – IF INHALED: P322 – Specific measures (see on this label).	C W 3 66
P305 – IF IN EYES: P322 – Specific measures (see on this label).	C W 3 67
P306 – IF ON CLOTHING: P322 – Specific measures (see on this label).	C W 3 68
P307 – IF exposed: P322 – Specific measures (see on this label).	C W 3 69
P308 – IF exposed or concerned: P322 – Specific measures (see on this label).	C W 3 70
P309 – IF exposed or if you feel unwell: P322 – Specific measures (see on this label).	C W 3 71
P307 – IF exposed: P330 – Rinse mouth.	C W 3 72
P308 – IF exposed or concerned: P330 – Rinse mouth.	C W 3 73
P309 – IF exposed or if you feel unwell: P330 – Rinse mouth.	C W 3 74
P307 – IF exposed: P331 – Do NOT induce vomiting.	C W 3 75
P308 – IF exposed or concerned: P331 – Do NOT induce vomiting.	C W 3 76
P309 – IF exposed or if you feel unwell: P331 – Do NOT induce vomiting.	C W 3 77
P333 – If skin irritation occurs or rash occurs: P334 – Immerse in cool water/wrap in wet bandages.	C W 3 78
P302 – IF ON SKIN: P334 – Immerse in cool water/wrap in wet bandages.	C W 3 79
P303 – IF ON SKIN (or hair): P334 – Immerse in cool water /wrap in wet bandages.	C W 3 80
P337 – If eye irritation persists: P334 – Immerse in cool water /wrap in wet bandages.	C W 3 81

P305 – IF IN EYES: P334 – Immerse in cool water/wrap in wet bandages.	C W 3 82
P333 – If skin irritation occurs or rash occurs: P335 – Brush off loose particles from skin.	C W 3 83
P302 – IF ON SKIN: P335 – Brush off loose particles from skin.	C W 3 84
P303 – IF ON SKIN (or hair): P335 – Brush off loose particles from skin.	C W 3 85
P306 – IF ON CLOTHING: P335 – Brush off loose particles from skin.	C W 3 86
P307 – IF exposed: P335 – Brush off loose particles from skin.	C W 3 87
P308 – IF exposed or concerned: P335 – Brush off loose particles from skin.	C W 3 88
P309 – IF exposed or if you feel unwell: P335 – Brush off loose particles from skin.	C W 3 89
P333 – If skin irritation occurs or rash occurs: P336 – Thaw frosted parts with lukewarm water. Do no rub affected area.	C W 3 90
P302 – IF ON SKIN: P336 – Thaw frosted parts with lukewarm water. Do no rub affected area.	C W 3 91
P303 – IF ON SKIN (or hair): P336 – Thaw frosted parts with lukewarm water. Do no rub affected area.	C W 3 92
P305 – IF IN EYES: P336 – Thaw frosted parts with lukewarm water. Do no rub affected area.	C W 3 93
P307 – IF exposed: P336 – Thaw frosted parts with lukewarm water. Do no rub affected area.	C W 3 94
P308 – IF exposed or concerned: P336 – Thaw frosted parts with lukewarm water. Do no rub affected area.	C W 3 95
P309 – IF exposed or if you feel unwell: P336 – Thaw frosted parts with lukewarm water. Do no rub affected area.	C W 3 96
P305 – IF IN EYES: P338 – Remove contact lenses, if present and easy to do. Continue rinsing.	C W 3 97
P307 – IF exposed: P338 – Remove contact lenses, if present and easy to do. Continue rinsing.	C W 3 98

P308 – IF exposed or concerned: P338 – Remove contact lenses, if present and easy to do. Continue rinsing.	C W 3 99
P309 – IF exposed or if you feel unwell: P338 – Remove contact lenses, if present and easy to do. Continue rinsing.	C W 4 00
P304 – IF INHALED: P340 – Remove victim to fresh air and keep at rest in a position comfortable for breathing.	C W 4 01
P307 – IF exposed: P340 – Remove victim to fresh air and keep at rest in a position comfortable for breathing.	C W 4 02
P308 – IF exposed or concerned: P340 – Remove victim to fresh air and keep at rest in a position comfortable for breathing.	C W 4 03
P309 – IF exposed or if you feel unwell: P340 – Remove victim to fresh air and keep at rest in a position comfortable for breathing.	C W 4 04
P332 – If skin irritation occurs: P350 – Gently wash with plenty of soap and water.	C W 4 05
P302 – IF ON SKIN: P350 – Gently wash with plenty of soap and water.	C W 4 06
P303 – IF ON SKIN (or hair): P350 – Gently wash with plenty of soap and water.	C W 4 07
P306 – IF ON CLOTHING: P350 – Gently wash with plenty of soap and water.	C W 4 08
P307 – IF exposed: P350 – Gently wash with plenty of soap and water.	C W 4 09
P308 – IF exposed or concerned: P350 – Gently wash with plenty of soap and water.	C W 4 10
P309 – IF exposed or if you feel unwell: P350 – Gently wash with plenty of soap and water.	C W 4 11
P333 – If skin irritation or rash occurs: P351 – Rinse cautiously with water for several minutes.	C W 4 12
P332 – If skin irritation occurs: P351 – Rinse cautiously with water for several minutes.	C W 4 13
P302 – IF ON SKIN: P351 – Rinse cautiously with water for several minutes.	C W 4 14
P303 – IF ON SKIN (or hair): P351 – Rinse cautiously with water for several minutes.	C W 4 15

P305 – IF IN EYES: P351 – Rinse cautiously with water for several minutes.	C W 4 16
P306 – IF ON CLOTHING: P351 – Rinse cautiously with water for several minutes.	C W 4 17
P307 – IF exposed: P351 – Rinse cautiously with water for several minutes.	C W 4 18
P308 – IF exposed or concerned: P351 – Rinse cautiously with water for several minutes.	C W 4 19
P309 – IF exposed or if you feel unwell: P351 – Rinse cautiously with water for several minutes.	C W 4 20
P332 – If skin irritation occurs: P352 – Wash with plenty of soap and water.	C W 4 21
P302 – IF ON SKIN: P352 – Wash with plenty of soap and water.	C W 4 22
P303 – IF ON SKIN (or hair): P352 – Wash with plenty of soap and water.	C W 4 23
P306 – IF ON CLOTHING: P352 – Wash with plenty of soap and water.	C W 4 24
P307 – IF exposed: P352 – Wash with plenty of soap and water.	C W 4 25
P308 – IF exposed or concerned: P352 – Wash with plenty of soap and water.	C W 4 26
P309 – IF exposed or if you feel unwell: P352 – Wash with plenty of soap and water.	C W 4 27
P332 – If skin irritation occurs: P353 – Rinse skin with water /shower.	C W 4 28
P302 – IF ON SKIN: P353 – Rinse skin with water/shower.	C W 4 29
P303 – IF ON SKIN (or hair): P353 – Rinse skin with water /shower.	C W 4 30
P306 – IF ON CLOTHING: P353 – Rinse skin with water /shower.	C W 4 31
P307 – IF exposed: P353 – Rinse skin with water/shower.	C W 4 32

P308 – IF exposed or concerned: P353 – Rinse skin with water /shower.	C W 4 33
P309 – IF exposed or if you feel unwell: P353 – Rinse skin with water/shower.	C W 4 34
P332 – If skin irritation occurs: P360 – Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.	C W 4 35
P302 – IF ON SKIN: P360 – Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.	C W 4 36
P303 – IF ON SKIN (or hair): P360 – Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.	C W 4 37
P306 – IF ON CLOTHING: P360 – Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.	C W 4 38
P307 – IF exposed: P360 – Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.	C W 4 39
P308 – IF exposed or concerned: P360 – Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.	C W 4 40
P309 – IF exposed or if you feel unwell: P360 – Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.	C W 4 41
P332 – If skin irritation occurs: P361 – Remove/Take off immediately all contaminated clothing.	C W 4 42
P302 – IF ON SKIN: P361 – Remove/Take off immediately all contaminated clothing.	C W 4 43
P303 – IF ON SKIN (or hair): P361 – Remove/Take off immediately all contaminated clothing.	C W 4 44
P306 – IF ON CLOTHING: P361 – Remove/Take off immediately all contaminated clothing.	C W 4 45
P307 – IF exposed: P361 – Remove/Take off immediately all contaminated clothing.	C W 4 46
P308 – IF exposed or concerned: P361 – Remove/Take off immediately all contaminated clothing.	C W 4 47
P309 – IF exposed or if you feel unwell: P361 – Remove/Take off immediately all contaminated clothing.	C W 4 48
P332 – If skin irritation occurs: P362 – Take off contaminated clothing and wash before reuse.	C W 4 49

P302 – IF ON SKIN: P362 – Take off contaminated clothing and wash before reuse.	C W 4 50
P303 – IF ON SKIN (or hair): P362 – Take off contaminated clothing and wash before reuse.	C W 4 51
P306 – IF ON CLOTHING: P362 – Take off contaminated clothing and wash before reuse.	C W 4 52
P307 – IF exposed: P362 – Take off contaminated clothing and wash before reuse.	C W 4 53
P308 – IF exposed or concerned: P362 – Take off contaminated clothing and wash before reuse.	C W 4 54
P309 – IF exposed or if you feel unwell: P362 – Take off contaminated clothing and wash before reuse.	C W 4 55
P332 – If skin irritation occurs: P363 – Wash contaminated clothing before reuse.	C W 4 56
P302 – IF ON SKIN: P363 – Wash contaminated clothing before reuse.	C W 4 57
P303 – IF ON SKIN (or hair): P363 – Wash contaminated clothing before reuse.	C W 4 58
P306 – IF ON CLOTHING: P363 – Wash contaminated clothing before reuse.	C W 4 59
P307 – IF exposed: P363 – Wash contaminated clothing before reuse.	C W 4 60
P308 – IF exposed or concerned: P363 – Wash contaminated clothing before reuse.	C W 4 61
P309 – IF exposed or if you feel unwell: P363 – Wash contaminated clothing before reuse.	C W 4 62
P371 – In case of major fire and large quantities: P374 – Fight fire with normal precautions from a reasonable distance.	C W 4 63
P371 – In case of major fire and large quantities: P375 – Fight fire remotely due to the risk of explosion.	C W 4 64
P371 – In case of major fire and large quantities: P380 – Evacuate area.	C W 4 65
P371 – In case of major fire and large quantities: P381 – Eliminate all ignition sources if safe to do so.	C W 4 66

OTHER **	C W 9 99
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** : requires to provide additional free text with translations

BR-UDID-805 : Critical Warnings -
ENUM_UDID_CriticalWarnings (Part I)

Sep 27,
2021

RESOLVED

Label	V a l u e	N o t e s
Do not resterilize	C W 0 01	
Defibrillation-proof type B applied part	C W 0 06	
Do not use if package is damaged	C W 0 07	
Biological risks	C W 0 08	
Do not re-use	C W 0 09	
Consult instructions for use	C W 0 10	
Caution	C W 0 11	
Caution: Electrostatic sensitive, do not touch directly.	C W 0 12	
Radiation of laser apparatus	C W 0 13	
Type BF applied part	C W 0 14	
Defibrillation-proof type BF applied part	C W 0 15	
Type B applied part	C W 0 16	
Defibrillation-proof type CF applied part	C W 0 17	

Refer to instruction manual/booklet	C W 0 18
Do not sterilize	C W 0 20
Do not cut	C W 0 22
Consider hazards from magnetic fields	C W 0 23
Do not store near magnets or magnetic devices	C W 0 24
MR SAFE	C W 0 25
MR CONDITIONAL	C W 0 26
MR UNSAFE	C W 0 27
Exposure to radiation when using the device	C W 0 28
Caution, sharp edges	C W 0 29
Consult healthcare professional before use	C W 0 30
Implant timeframe limitations	C W 0 31
Do not use past indicated date	C W 0 32
Restriction in use of des infectors,	C W 0 35
Restrictions in use for combination of other devices	C W 0 36
GHS01 – Danger - Unstable, Explosive	C W 0 37
GHS02 - Danger or Warning - Flammable	C W 0 38

GHS03- Danger or Warning -Oxidising	C W 0 39
GHS04- Warning -Compressed gas	C W 0 40
GHS05 -Danger or Warning -Corrosive cat. 1	C W 0 41
GHS06 – Danger -Toxic cat. 1 - 3	C W 0 42
GHS07 - Warning -Toxic cat. 4, Irritant cat. 2 or 3, Lower systemic health hazards	C W 0 43
GHS08 - Danger or Warning - Systemic health hazards	C W 0 44
GHS09 - Warning (for cat. 1)- (for cat. 2 no signal word) Environment	C W 0 45
H200 – Unstable explosives.	C W 0 46
H201 – Explosive; mass explosion hazard.	C W 0 47
H202 – Explosive, severe projection hazard.	C W 0 48
H203 – Explosive; fire, blast or projection hazard.	C W 0 49
H204 – Fire or projection hazard.	C W 0 50
H205 – May mass explode in fire.	C W 0 51
H220 – Extremely flammable gas.	C W 0 52
H221 – Flammable gas.	C W 0 53
H222 – Extremely flammable aerosol.	C W 0 54
H223 – Flammable aerosol.	C W 0 55

H224 – Extremely flammable liquid and vapour.	C W 0 56
H225 – Highly flammable liquid and vapour.	C W 0 57
H226 – Flammable liquid and vapour.	C W 0 58
H228 – Flammable solid.	C W 0 59
H240 – Heating may cause an explosion.	C W 0 60
H241 – Heating may cause a fire or explosion.	C W 0 61
H242 – Heating may cause a fire.	C W 0 62
H250 – Catches fire spontaneously if exposed to air.	C W 0 63
H251 – Self-heating; may catch fire.	C W 0 64
H252 – Self-heating in large quantities; may catch fire.	C W 0 65
H260 – In contact with water releases flammable gases which may ignite spontaneously.	C W 0 66
H261 – In contact with water releases flammable gases.	C W 0 67
H270 – May cause or intensify fire; oxidiser.	C W 0 68
H271 – May cause fire or explosion; strong oxidiser.	C W 0 69
H272 – May intensify fire; oxidiser.	C W 0 70
H280 – Contains gas under pressure; may explode if heated.	C W 0 71
H281 – Contains refrigerated gas; may cause cryogenic burns or injury.	C W 0 72

H290 – May be corrosive to metals.	C W 0 73
H300 – Fatal if swallowed.	C W 0 74
H301 – Toxic if swallowed.	C W 0 75
H302 – Harmful if swallowed.	C W 0 76
H304 – May be fatal if swallowed and enters airways.	C W 0 77
H310 – Fatal in contact with skin.	C W 0 78
H311 – Toxic in contact with skin.	C W 0 79
H312 – Harmful in contact with skin.	C W 0 80
H314 – Causes severe skin burns and eye damage.	C W 0 81
H315 – Causes skin irritation.	C W 0 82
H317 – May cause an allergic skin reaction.	C W 0 83
H318 – Causes serious eye damage.	C W 0 84
H319 – Causes serious eye irritation.	C W 0 85
H330 – Fatal if inhaled.	C W 0 86
H331 – Toxic if inhaled.	C W 0 87
H332 – Harmful if inhaled.	C W 0 88
H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled.	C W 0 89

H335 – May cause respiratory irritation.	C W 0 90
H336 – May cause drowsiness or dizziness.	C W 0 91
H340 – May cause genetic defects exposure cause the hazard>.	C W 0 92
H341 – Suspected of causing genetic defects.	C W 0 93
H350 – May cause cancer.	C W 0 94
H351 – Suspected of causing cancer.	C W 0 95
H360 – May damage fertility or the unborn child.	C W 0 96
H361 – Suspected of damaging fertility or the unborn child.	C W 0 97
H362 – May cause harm to breast-fed children.	C W 0 98
H370 – Causes damage to organs.	C W 0 99
H371 – May cause damage to organs.	C W 1 00
H372 – Causes damage to organs through prolonged or repeated exposure exposure cause the hazard>.	C W 1 01
H373 – May cause damage to organs through prolonged or repeated exposure.	C W 1 02
H400 – Very toxic to aquatic life.	C W 1 03
H410 – Very toxic to aquatic life with long lasting effects.	C W 1 04
H411 – Toxic to aquatic life with long lasting effects.	C W 1 05
H412 – Harmful to aquatic life with long lasting effects.	C W 1 06

H413 – May cause long lasting harmful effects to aquatic life.	C W 1 07
EUH 001 – Explosive when dry.	C W 1 08
EUH 006 – Explosive with or without contact with air.	C W 1 09
EUH 014 – Reacts violently with water.	C W 1 10
EUH 018 – In use, may form flammable/explosive vapour-air mixture.	C W 1 11
EUH 019 – May form explosive peroxides.	C W 1 12
EUH 044 – Risk of explosion if heated under confinement.	C W 1 13
EUH 029 – Contact with water liberates toxic gas.	C W 1 14
EUH 031 – Contact with acids liberates toxic gas.	C W 1 15
EUH 032 – Contact with acids liberates very toxic gas.	C W 1 16
EUH 066 – Repeated exposure may cause skin dryness or cracking.	C W 1 17
EUH 070 – Toxic by eye contact.	C W 1 18
EUH 071 – Corrosive to the respiratory tract.	C W 1 19
EUH 059 – Hazardous to the ozone layer.	C W 1 20
EUH 201 – Contains lead. Should not be used on surfaces liable to be chewed or sucked by children.	C W 1 21
EUH 201A – Warning! Contains lead.	C W 1 22
EUH 202 – Cyanoacrylate. Danger. Bonds skin and eyes in seconds. Keep out of the reach of children.	C W 1 23

EUH 203 – Contains chromium (VI). May produce an allergic reaction.	C W 1 24
EUH 204 – Contains isocyanates. May produce an allergic reaction.	C W 1 25
EUH 205 – Contains epoxy constituents. May produce an allergic reaction.	C W 1 26
EUH 206 – Warning! Do not use together with other products. May release dangerous gases (chlorine)	C W 1 27
EUH 207 – Warning! Contains cadmium. Dangerous fumes are formed during use. See information supplied by the manufacturer. Comply with the safety instructions.	C W 1 28
EUH 208 – Contains (name of sensitising substance). May produce an allergic reaction.	C W 1 29
EUH 209 – Can become highly flammable in use.	C W 1 30
EUH 209A – Can become flammable in use.	C W 1 31
EUH 210 – Safety data sheet available on request.	C W 1 32
EUH 401 – To avoid risks to human health and the environment, comply with the instructions for use.	C W 1 33
P101 – If medical advice is needed, have product container or label at hand.	C W 1 34
P102 – Keep out of reach of children.	C W 1 35
P103 – Read label before use.	C W 1 36
P201 – Obtain special instructions before use.	C W 1 37
P202 – Do not handle until all safety precautions have been read and understood.	C W 1 38
P210 – Keep away from heat/sparks/open flames/hot surfaces. — No smoking.	C W 1 39
P211 – Do not spray on an open flame or other ignition source.	C W 1 40

P220 – Keep/Store away from clothing/.../combustible materials.	C W 1 41
P221 – Take any precaution to avoid mixing with combustibles...	C W 1 42
P222 – Do not allow contact with air.	C W 1 43
P223 – Keep away from any possible contact with water, because of violent reaction and possible flash fire.	C W 1 44
P231 – Handle under inert gas.	C W 1 46
P232 – Protect from moisture.	C W 1 47
P233 – Keep container tightly closed.	C W 1 48
P234 – Keep only in original container.	C W 1 49
P235 – Keep cool.	C W 1 50
P240 – Ground/bond container and receiving equipment.	C W 1 51
P241 – Use explosion-proof electrical/ventilating/lighting/.../equipment.	C W 1 52
P242 – Use only non-sparking tools.	C W 1 53
P243 – Take precautionary measures against static discharge.	C W 1 54
P244 – Keep reduction valves free from grease and oil.	C W 1 55
P250 – Do not subject to grinding/shock/.../friction.	C W 1 56
P251 – Pressurized container: Do not pierce or burn, even after use.	C W 1 57
P260 – Do not breathe dust/fume/gas/mist/vapours/spray.	C W 1 58

P261 – Avoid breathing dust/fume/gas/mist/vapours/spray.	C W 1 59
P262 – Do not get in eyes, on skin, or on clothing.	C W 1 60
P263 – Avoid contact during pregnancy/while nursing.	C W 1 61
P264 – Wash thoroughly after handling.	C W 1 62
P270 – Do not eat, drink or smoke when using this product.	C W 1 63
P271 – Use only outdoors or in a well-ventilated area.	C W 1 64
P272 – Contaminated work clothing should not be allowed out of the workplace.	C W 1 65
P273 – Avoid release to the environment.	C W 1 66
P280 – Wear protective gloves/protective clothing/eye protection /face protection.	C W 1 67
P281 – Use personal protective equipment as required.	C W 1 68
P282 – Wear cold insulating gloves/face shield/eye protection.	C W 1 69
P283 – Wear fire/flame resistant/retardant clothing.	C W 1 70
P284 – Wear respiratory protection.	C W 1 71
P285 – In case of inadequate ventilation wear respiratory protection.	C W 1 72
P231 + P232 – Handle under inert gas. Protect from moisture.	C W 1 73
P301 – IF SWALLOWED: P310 – Immediately call a POISON CENTER or doctor/physician.	C W 1 75
P302 – IF ON SKIN: P310 – Immediately call a POISON CENTER or doctor/physician.	C W 1 76

P303 – IF ON SKIN (or hair): P310 – Immediately call a POISON CENTER or doctor/physician.	C W 1 77
P304 – IF INHALED: P310 – Immediately call a POISON CENTER or doctor/physician.	C W 1 78
P305 – IF IN EYES: P310 – Immediately call a POISON CENTER or doctor/physician.	C W 1 79
P306 – IF ON CLOTHING: P312 – Call a POISON CENTER or doctor/physician if you feel unwell.	C W 1 80
P307 – IF exposed: P310 – Immediately call a POISON CENTER or doctor/physician.	C W 1 81
P308 – IF exposed or concerned: P310 – Immediately call a POISON CENTER or doctor/physician.	C W 1 82
P309 – IF exposed or if you feel unwell: P310 – Immediately call a POISON CENTER or doctor/physician.	C W 1 83
P342 – If experiencing respiratory symptoms: P310 – Immediately call a POISON CENTER or doctor/physician.	C W 1 84
P342 – If experiencing respiratory symptoms: P311 – Call a POISON CENTER or doctor/physician.	C W 1 85
P342 – If experiencing respiratory symptoms: P312 – Call a POISON CENTER or doctor/physician if you feel unwell.	C W 1 86
P342 – If experiencing respiratory symptoms: P313 – Get medical advice/attention.	C W 1 87
P342 – If experiencing respiratory symptoms: P314 – Get medical advice/attention if you feel unwell.	C W 1 88
P342 – If experiencing respiratory symptoms: P315 – Get immediate medical advice/attention.	C W 1 89
P342 – If experiencing respiratory symptoms: P320 – Specific treatment is urgent (see on this label).	C W 1 90
P342 – If experiencing respiratory symptoms: P321 – Specific treatment (see on this label).	C W 1 91
P342 – If experiencing respiratory symptoms: P322 – Specific measures (see on this label).	C W 1 92
P301 – IF SWALLOWED: P330 – Rinse mouth.	C W 1 93

P301 – IF SWALLOWED: P331 – Do NOT induce vomiting.	C W 1 94
P332 – If skin irritation occurs: P322 – Specific measures (see on this label).	C W 1 95
P333 – If skin irritation or rash occurs: P322 – Specific measures (see on this label).	C W 1 96
P332 – If skin irritation occurs: P334 – Immerse in cool water /wrap in wet bandages.	C W 1 97
P332 – If skin irritation occurs: P335 – Brush off loose particles from skin.	C W 1 98
P332 – If skin irritation occurs: P336 – Thaw frosted parts with lukewarm water. Do no rub affected area.	C W 1 99
P337 – If eye irritation persists: P338 – Remove contact lenses, if present and easy to do. Continue rinsing.	C W 2 01
P342 – If experiencing respiratory symptoms: P340 – Remove victim to fresh air and keep at rest in a position comfortable for breathing.	C W 2 02
P341 – If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.	C W 2 03
P333 – If skin irritation or rash occurs: P350 – Gently wash with plenty of soap and water.	C W 2 06
P337 – If eye irritation persists: P351 – Rinse cautiously with water for several minutes.	C W 2 07
P333 – If skin irritation or rash occurs: P352 – Wash with plenty of soap and water.	C W 2 08
P333 – If skin irritation or rash occurs: P353 – Rinse skin with water/shower.	C W 2 09
P333 – If skin irritation or rash occurs: P360 – Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.	C W 2 10
P333 – If skin irritation or rash occurs: P361 – Remove/Take off immediately all contaminated clothing.	C W 2 11
P333 – If skin irritation or rash occurs: P362 – Take off contaminated clothing and wash before reuse.	C W 2 12
P333 – If skin irritation or rash occurs: P363 – Wash contaminated clothing before reuse.	C W 2 13

P372 – Explosion risk in case of fire.	C W 2 16
P373 – DO NOT fight fire when fire reaches explosives.	C W 2 17
P370 – In case of fire: P374 – Fight fire with normal precautions from a reasonable distance.	C W 2 18
P370 – In case of fire: P375 – Fight fire remotely due to the risk of explosion.	C W 2 19
P376 – Stop leak if safe to do so.	C W 2 20
P377 – Leaking gas fire: Do not extinguish, unless leak can be stopped safely.	C W 2 21
P370 – In case of fire: P380 – Evacuate area.	C W 2 23
P370 – In case of fire: P381 – Eliminate all ignition sources if safe to do so.	C W 2 24
P390 – Absorb spillage to prevent material damage.	C W 2 25
P391 – Collect spillage.	C W 2 26
Do not Use Tap Water	C W 2 54
Do Not use saliva	C W 2 55
Warning; Crushing of hands	C W 2 57
Warning; Hot surface	C W 2 58
Warning; Electricity	C W 2 59
Warning; Counterrotating rollers	C W 2 60
Warning; Optical radiation	C W 2 61

Single patient multiple use	C W 2 62
Contains human blood or plasma derivatives	C W 2 63
Contains a medicinal substance	C W 2 64
Contains hazardous substances	C W 2 65
Contains biological material of human origin	C W 2 66
Contains biological material of animal origin	C W 2 67
H229 Pressurized container: may burst if heated	C W 2 68
H230 May react explosively even in the absence of air	C W 2 69
H231 May react explosively even in the absence of air at elevated pressure and/or temperature	C W 2 70
H420 Harms public health and the environment by destroying ozone in the upper atmosphere	C W 2 71
P364 And wash it before reuse.	C W 2 72
Caution, risk of electric shock	C W 2 73
Non-ionizing electromagnetic radiation	C W 2 74
Ask your pharmacist or doctor for advice before using or taking the product (e.g. if pregnant or breastfeeding)	C W 2 75
Potential Interactions with other products (e.g. medicines, food)	C W 2 76
If any symptoms are troublesome or last more than a few days or if you notice any side effects not mentioned, please inform your doctor or pharmacist	C W 2 77
Avoid contact with non-sterile water	C W 2 78

P337 – If eye irritation persists: P310 – Immediately call a POISON CENTER or doctor/physician.	C W 2 79
P332 – If skin irritation occurs: P310 – Immediately call a POISON CENTER or doctor/physician.	C W 2 80
P333 – If skin irritation or rash occurs: P310 – Immediately call a POISON CENTER or doctor/physician.	C W 2 81
P337 – If eye irritation persists: P311 – Call a POISON CENTER or doctor/physician.	C W 2 82
P332 – If skin irritation occurs: P311 – Call a POISON CENTER or doctor/physician.	C W 2 83
P333 – If skin irritation or rash occurs: P311 – Call a POISON CENTER or doctor/physician.	C W 2 84
P301 – IF SWALLOWED: P311 – Call a POISON CENTER or doctor/physician.	C W 2 85
P302 – IF ON SKIN: P311 – Call a POISON CENTER or doctor/physician.	C W 2 86
P303 – IF ON SKIN (or hair): P311 – Call a POISON CENTER or doctor/physician.	C W 2 87
P304 – IF INHALED: P311 – Call a POISON CENTER or doctor/physician.	C W 2 88
P305 – IF IN EYES: P311 – Call a POISON CENTER or doctor/physician.	C W 2 89
P307 – IF exposed: P311 – Call a POISON CENTER or doctor/physician.	C W 2 90
P308 – IF exposed or concerned: P311 – Call a POISON CENTER or doctor/physician.	C W 2 91
P309 – IF exposed or if you feel unwell: P311 – Call a POISON CENTER or doctor/physician.	C W 2 92
P337 – If eye irritation persists: P312 – Call a POISON CENTER or doctor/physician if you feel unwell.	C W 2 93
P332 – If skin irritation occurs: P312 – Call a POISON CENTER or doctor/physician if you feel unwell.	C W 2 94
P333 – If skin irritation or rash occurs: P312 – Call a POISON CENTER or doctor/physician if you feel unwell.	C W 2 95

P301 – IF SWALLOWED: P312 – Call a POISON CENTER or doctor/physician if you feel unwell.	C W 2 96
P302 – IF ON SKIN: P312 – Call a POISON CENTER or doctor /physician if you feel unwell.	C W 2 97
P303 – IF ON SKIN (or hair): P312 – Call a POISON CENTER or doctor/physician if you feel unwell.	C W 2 98
P304 – IF INHALED: P312 – Call a POISON CENTER or doctor /physician if you feel unwell.	C W 2 99
P305 – IF IN EYES: P312 – Call a POISON CENTER or doctor /physician if you feel unwell.	C W 3 00

BR-UDID-806 : Device Recall Scope -
ENUM_UDID_DeviceRecallScope

Sep 27,
2021

RESOLVED

Label	Value	Notes	Sort Order
Lot Number	LOT_NUMBER		1
Serial Number	SERIAL_NUMBER		2
Software Version	SOFTWARE_VERSION		3
UDI-DI	UDI-DI		4

BR-UDID-807 : Device Status -
ENUM_UDID_DeviceStatus

Sep 27,
2021

RESOLVED

Label	Value	Notes	Sort Order
On the EU market	ON_THE_MARKET		1
No longer placed on the EU market	NO_LONGER_PLACED_ON_THE_MARKET		2
Not Intended for EU market	NOT_INTENDED_FOR_EU_MARKET		3

BR-UDID-808 : Device Sub Status -
ENUM_UDID_DeviceSubStatus

Sep 27,
2021

RESOLVED

Label	Value	Notes	Sort Order
Recalled	RECALLED		1
Field safety corrective action initiated	FIELD_SAFETY_CORRECTIVE_ACTION_INITIATED		2

BR-UDID-809 : Intruction for Use Type -
ENUM_UDID_IFUType

Sep 27,
2021

RESOLVED

Label	Value	Notes	Sort Order
Critical Warnings or Contra Indications	CW		1
Storage and Handling Conditions	SHC		2

BR-UDID-811 : Multi-Component Device Types -
ENUM_UDID_DeviceSystemProcedurePackType

Sep 27,
2021

RESOLVED

Label	Value	Notes	Sort Order
System which is a Device in itself	SYSTEM	Applicable for Devices having Applicable Legislation : MDR, MDD, AIMDD	
Procedure pack which is a Device in itself	PROCEDURE_PACK	Applicable for Devices having Applicable Legislation : MDR, MDD, AIMDD	
DEVICE	DEVICE	Applicable for Devices having Applicable Legislation : MDR, MDD, AIMDD	

BR-UDID-812 : Non Medical Device Types -
ENUM_UDID_NonMedicalDeviceType

Nov 05,
2021

RESOLVED

Label	Value	Notes	Sort Order
Brain Electrostimulation	BRAIN_ELECTROSTIMULATION		1
Contact Lenses	CONTACT_LENSSES		2
EMR	EMR		3
EQUIPMENT FOR ADIPOSE TISSUE	EQUIPMENT_FOR_ADIPOSE_TISSUE		4
FILLING BY INJECTION	FILLING_BY_INJECTION		5
PRODUCT IN BODY	PRODUCT_IN_BODY		6

BR-UDID-813 : Production Identifier -
ENUM_UDID_ProductionIdentifier

Jan 17,
2022

RESOLVED

Label	Value	Notes	Sort Order
BATCH NUMBER	BATCH_NUMBER		1
SERIAL NUMBER	SERIALISATION_NUMBER		2
MANUFACTURING DATE	MANUFACTURING_DATE		3
EXPIRATION DATE	EXPIRATION_DATE		4
SOFTWARE IDENTIFICATION	SOFTWARE_IDENTIFICATION		5

BR-UDID-814 : Public Filter Device Type -
ENUM_UDID_PublicFilter_DeviceType

Sep 27,
2021

RESOLVED

Label	Value	Notes	Sort Order
Implantable (MDR,MDD, AIMDD)	Implantable		1
Implantable Exception (sutures, staples , etc.) (MDR)	Implantable_exception		1.1
Active Device (MDR,MDD, AIMDD)	Active_Device		2
Measuring function (MDR,MDD, AIMDD)	Measuring_function		3
Reusable surgical instrument (MDR,MDD, AIMDD)	Reusable_surgical_instrument		4

Intended to administer or remove medicinal substance (MDR,MDD, AIMDD)	Intended_to_administer_or_remove_medicinal_substance	5
Intended for self testing (IVDR /IVDD)	Intended_for_self_testing	6
Intended for near-patient testing (IVDR/IVDD)	Intended_for_near-patient_testing	7
Companion Diagnostics (IVDR /IVDD)	Companion_Diagnostics	8
Reagent (IVDR/IVDD)	Reagent	9
Professional Testing (IVDR/IVDD)	Professional_Testing	10
Instrument (IVDR/IVDD)	Instrument	1 0.1
Reprocessed (MDR,MDD, AIMDD)	Reprocessed	11
Containing latex (MDR,MDD, AIMDD)	Containing_latex	12
Sterile (MDR,MDD, AIMDD)	Sterile	13
Needs Sterilisation (MDR,MDD, AIMDD)	Needs_Sterilisation	14
CMR Substances (MDR)	CMR_Substances	15
Endocrine disrupting Substances (MDR)	Endocrine_disrupting_Substances	16
Substances considered medicinal product (MDR,MDD, AIMDD)	Substances_considered_medicinal_product	17
Substances considered medicinal product derived from human blood or plasma (MDR,MDD, AIMDD)	Substances_considered_medicinal_product_derived_from_human_blood_or_plasma	18
Tissues or Cells from human origin ((MDR,MDD, AIMDD/IVDR/IVDD)	Tissues_or_Cells_from_human_origin	19
Tissues or Cells from animal origin ((MDR,MDD, AIMDD/IVDR /IVDD)	Tissues_or_Cells_from_animal_origin	20
Cells or Substances of microbial origin (IVDR/IVDD)	Cells_or_Substances_of_microbial_origin	21
'New Device' (IVDR)	'New_Device'	22
KIT (IVDR/IVDD)	KIT	23
System as Device (MDR,MDD, AIMDD)	System_as_Device	24
Procedure Pack as Device (MDR, MDD, AIMDD)	Procedure_Pack_as_Device	25
Special Device (Software) (MDR, MDD, AIMDD/ IVDR/IVDD)	Software	26
Special Device (Standard soft contact lenses) (MDR,MDD, AIMDD)	Standard_soft_contact_lenses	27
Special Device (Rigid Gas Permeable (RGP) & Made-to-Order Soft Contact Lenses) (MDR, MDD, AIMDD)	Rigid_Gas_Permeable_(RGP)_&_Made-to-Order_Soft_Contact_Lenses	28
Special Device (Orthopaedic) (MDR,MDD, AIMDD)	Orthopaedic	29

Label	Value	Notes
MDR	MDR	
IVDR	IVDR	

BR-UDID-816 : Public Filter System or Procedure Pack -
ENUM_UDID_PublicFilter_SystemProcedurePack

Sep 27,
2021

RESOLVED

Label	Value	Notes
Device	Device	
System	System	
Procedure Pack	Procedure_Pack	

BR-UDID-817 : Device Risk Class -
ENUM_UDID_RiskClass

Jan 12,
2022

RESOLVED

Label	Value	Notes
Class A	CLASS_A	Applicable for Applicable Legislation : IVDR
Class B	CLASS_B	Applicable for Applicable Legislation : IVDR
Class C	CLASS_C	Applicable for Applicable Legislation : IVDR
Class D	CLASS_D	Applicable for Applicable Legislation : IVDR
Class I	CLASS_I	Applicable for Applicable Legislation : MDR, MDD (and System or Procedure Packs)
Class IIa	CLASS_IIA	Applicable for Applicable Legislation : MDR, MDD (and System or Procedure Packs)
Class IIb	CLASS_IIB	Applicable for Applicable Legislation : MDR, MDD (and System or Procedure Packs)
Class III	CLASS_III	Applicable for Applicable Legislation : MDR, MDD (and System or Procedure Packs)
IVD AnnexII List A	IVD_ANNEX_I I_LIST_A	Applicable for Applicable Legislation : IVDD
IVD Annex II List B	IVD_ANNEX_I I_LIST_b	Applicable for Applicable Legislation : IVDD
IVD devices for self- testing	IVD_DEVICES _SELF_TESTI NG	Applicable for Applicable Legislation : IVDD
IVD General	IVD_GENERAL	Applicable for Applicable Legislation : IVDD
AIMDD	AIMDD	Applicable for Applicable Legislation : AIMDD

BR-UDID-818 : Special Device Type -
ENUM_UDID_SpecialDevice

Mar 10,
2022

RESOLVED

Label	Value	Order Number	Notes
Software	IVDR_SOFTWARE	1	Applicable for the following Applicable Legislations : IVDR
	IVDD_SOFTWARE		Applicable for the following Applicable Legislations : IVDD
	MDR_SOFTWARE	1	Applicable for the following Applicable Legislations : MDR
	MDD_SOFTWARE	1	Applicable for the following Applicable Legislations : MDD
	AIMDD_SOFTWARE	1	Applicable for the following Applicable Legislations : AIMDD
Standard soft contact lenses	MDR_STANDARD_SOFT_CONTACT_LENSSES	2	Applicable for the following Applicable Legislations : MDR
	MDD_STANDARD_SOFT_CONTACT_LENSE	2	Applicable for the following Applicable Legislations : MDD
Rigid Gas Permeable (RGP) Contact Lenses	MDR_RIGID_GAS_PERMEABLE	3	Applicable for the following Applicable Legislations : MDR
	MDD_RIGID_GAS_PERMEABLE	3	Applicable for the following Applicable Legislations : MDD
Made to order soft contact lenses	MDR_MADE_TO_ORDER	4	Applicable for the following Applicable Legislations : MDR
	MDD_MADE_TO_ORDER	4	Applicable for the following Applicable Legislations : MDD
Spectacle frames	MDR_SPECTACLES_FRAMES	5	Applicable for the following Applicable Legislations : MDR
	MDD_SPECTACLES_FRAMES	5	Applicable for the following Applicable Legislations : MDD
Spectacle lenses	MDR_SPECTACLES_LENSSES	6	Applicable for the following Applicable Legislations : MDR
	MDD_SPECTACLES_LENSSES		Applicable for the following Applicable Legislations : MDD
Ready-made reading spectacles	MDR_READY_MADE_SPECTACLES	7	Applicable for the following Applicable Legislations : MDR
	MDD_READY_MADE_SPECTACLES		Applicable for the following Applicable Legislations : MDD
Orthopedic	MDR_ORTHOPEDIC	8	Applicable for the following Applicable Legislations : MDR
	MDD_ORTHOPEDIC		Applicable for the following Applicable Legislations : MDD,
	AIMDD_ORTHOPEDIC		Applicable for the following Applicable Legislations : AIMDD

Name	Code	Notes
Fragile, handle with care	SH C001	
Keep away from sunlight	SH C002	
Protect from heat and radioactive sources	SH C003	
Protect from radioactive sources	SH C004	
Keep dry	SH C005	
Lower limit of temperature *	SH C006	
Upper limit of temperature *	SH C007	
Temperature limit *	SH C008	
Humidity limitation *	SH C009	
Atmospheric pressure limitation *	SH C010	
Dangerous voltage	SH C012	
P401 – Store at... *	SH C013	
P402 – Store in a dry place.	SH C014	
P403 – Store in a well-ventilated place.	SH C015	
P404 – Store in a closed container.	SH C016	
P405 – Store locked up.	SH C017	
P406 – Store in corrosive resistant/... container with a resistant inner liner.	SH C018	
P407 – Maintain air gap between stacks/pallets.	SH C019	
P411 – Store at temperatures not exceeding ... oC/...oF. *	SH C021	
P412 – Do not expose to temperatures exceeding 50 oC /122oF. *	SH C022	
P413 – Store bulk masses greater than ... kg/... lbs at temperatures not exceeding ... oC/...oF. *	SH C023	
P420 – Store away from other materials.	SH C024	
P422 – Store contents below ... *	SH C025	
Electrostatic sensitive devices	SH C033	
Do not sterilize	SH C035	
Do not freeze	SH C036	
Do not cut	SH C037	
Do not store near magnets or magnetic devices	SH C038	

Avoid contact with water	SH C042	
This way up	SH C044	
Period-after-opening ... *	SH C045	
Special Storage Conditions (see IFU)	SH C046	
Electrostatic sensitive devices	SH C047	
OTHER **	SH C099	

*: require an additional value that will not require translation

**: requires to provide additional free text with translations

BR-UDID-821 : Substance types -
ENUM_UDID_SubstType

Sep 27,
2021

RESOLVED

Label	Value	Notes	Sort Order
CMR SUBSTANCE	SUBST_1		1
ENDOCRINE SUBSTANCE	SUBST_2		2
MEDICINAL PRODUCT	SUBST_3		3
HUMAN PRODUCT	SUBST_4		4

BR-UDID-822 : System and Procedure Pack Type -
ENUM_UDID_SystemProcedurePackType

Sep 27,
2021

RESOLVED

Label	Value	Notes	Sort Order
System	SYSTEM		1
Procedure Pack	PROCEDURE_PACK		2

BR-UDID-823 : Workflow State -
ENUM_UDID_WorkflowState

Sep 27,
2021

RESOLVED

Label	Value	Notes	Sort Order
Draft	DRAFT		1
Submitted	SUBMITTED		2
Registered	REGISTERED		3
Discarded	DISCARDED		4

BR-UDID-824 : Certificate Types used for Device
Certificate Information -
Enum_UDI_Device_Certificate_Info_CertTypes

Sep 27,
2021

RESOLVED

The Certificate types that can be returned by EUDAMED in the Device Certificate information section (actual Certificates linked to Devices in EUDAMED) can be the following - based on the Applicable legislation:

For MDR Applicable Legislation, the types of the Certificate can be:

Label	Value	Notes
EU Quality Management System certificate (Annex IX Chapter I)	MDR_QUALITY_MANAGEMENT_SYSTEM	
EU Technical Documentation certificate (Annex IX Chapter II)	MDR_TECHNICAL_DOCUMENTATION	
EU Type Examination certificate (Annex X)	MDR_TYPE_EXAMINATION	
EU Quality Assurance certificate (Annex XI Part A)	MDR_QUALITY_ASSURANCE	
EU Product verification certificate (Annex XI Part B)	MDR_PRODUCT_VERIFICATION	

For IVDR Applicable Legislation, the types of the Certificate can be:

Label	Value	Notes
EU Quality Management System certificate (Annex IX Chapter I)	IVDR_QUALITY_MANAGEMENT_SYSTEM	
EU Technical Documentation certificate (Annex IX Chapter II)	IVDR_TECHNICAL_DOCUMENTATION	
EU Type Examination certificate (Annex X)	IVDR_TYPE_EXAMINATION	
EU Production Quality Assurance certificate (Annex XI)	IVDR_PRODUCTION_QUALITY_ASSURANCE	

For MDD Applicable Legislation, the types of the Certificate can be:

Label	Value	Notes
Directive 93/42/EEC Annex II excluding section 4	MDD_II_ex_4	
Directive 93/42/EEC Annex II section 4	MDD_II_4	
Directive 93/42/EEC Annex III	MDD_III	
Directive 93/42/EEC Annex IV	MDD_IV	
Directive 93/42/EEC Annex V	MDD_V	
Directive 93/42/EEC Annex VI	MDD_VI	

For AIMDD Applicable Legislation, the types of the Certificate can be:

Label	Value	Notes
Directive 90/385/EEC Annex 2 excluding section 4	AIMDD_II_ex_4	
Directive 90/385/EEC Annex 2 section 4	AIMDD_II_4	
Directive 90/385/EEC Annex 3	AIMDD_III	
Directive 90/385/EEC Annex 4	AIMDD_IV	
Directive 90/385/EEC Annex 5	AIMDD_V	

For IVDD Applicable Legislation, the types of the Certificate can be:

Label	Value	Notes
Directive 98/79/EC Annex III section 6	IVDD_III_6	
Directive 98/79/EC Annex IV excl. section 4 and 6	IVDD_IV_ex_4-6	
Directive 98/79/EC Annex IV section 4	IVDD_IV_4	
Directive 98/79/EC Annex IV section 6	IVDD_IV_6	
Directive 98/79/EC Annex V	IVDD_V	
Directive 98/79/EC Annex VI	IVDD_VI	
Directive 98/79/EC Annex VII excluding section 5	IVDD_VII_ex_5	
Directive 98/79/EC Annex VII section 5	IVDD_VII_5	

26 issues