

	Document title: Label master file CU01		
	ID: REC-0892	Version: 0.10	Approved date: Valid date:
	Issued by:		Approved by:

LABEL MASTER FILE

CU01<CCDDD>

DRAFT

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1 Purpose

The purpose of this document is to describe inputs and justification to the product labelling of the CU01. The document will serve as input to the printing and labelling on the product created by the legal manufacturer of the drug device combination product.

The document shows what information is required on the product for the medical device CU01 configured for *<Product ID>*, *<Drug company>*.

2 Scope

This document covers the product CU01*<CCDDD>* part of ODM01*<CCDDD>* , for details see [1].

3 Abbreviations and terms

Abbreviation	Meaning
ODM01 <i><CCDDD></i>	OnDosis Dosage manager Generation 1, configured for <i><Drug company></i> .
CU01 <i><CCDDD></i>	OnDosis Control unit Generation 1, configured for <i><Drug company></i> .
<i><Name></i> .	<i><Drug company></i> ., Legal manufacturer
<i><Drug></i> .	<i><Meaning></i>
IP	Ingress Protection

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4 Product label General information

The following input is required for defining the labelling for the product label. This master file, is considered to be the content to the labelling of the product.

NOTE!: *Blue italic text* in the released document is guide text and shall not be included in the labelling.

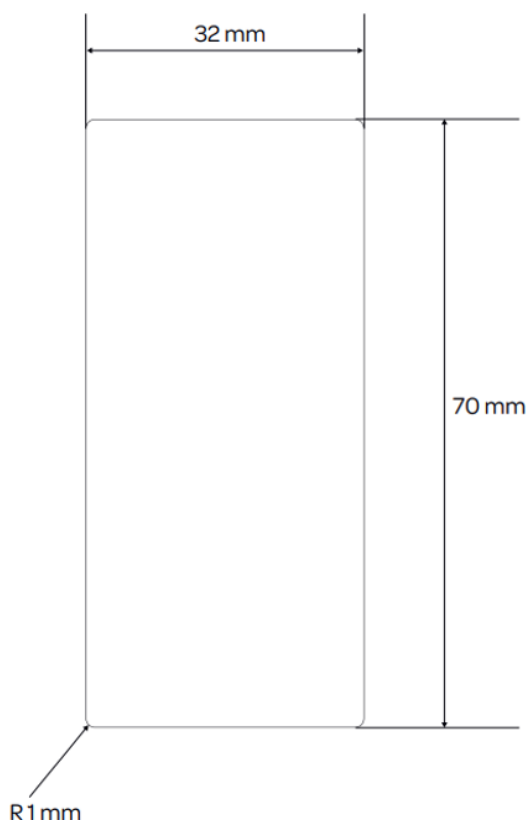
4.1 Branding guidelines (Marketing input)

NA, the branding guidelines will be defined by the legal manufacturer

4.2 Material

Product label material shall be biocompatible paper based with adhesive. Ink for the label shall be in biocompatible ink suitable for medical devices.

4.3 Size



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5 Labelling

Symbols used shall be according to ISO15223-1

Size on text (letters, numbers and special characters) must be readable.

5.1 Product Labelling

*The following information is required to be printed on the product Label
Symbols and text required to be visible on the product packaging*

Information	Symbol	Text to accompany the symbol
Drug brand name		<i>Defined by the legal manufacturer</i>
Refer to instruction's manual		
Power supply		5V  500 mA / USB-C
FCC		FCC ID: 2A663-CU01
ISED		IC ID: 28707-CU01
HVIN		CU01
IP		IP22
Radio antenna		
Legal manufacturer		<i>Defined by the legal manufacturer</i>
Prescription device		
Class II equipment		
Date of manufacture		YYYY/MM/DD
UDI (Optional)		(01)12345678910111 (10)1234 (21)CU01<CCDDDD1AAAAXXXXXX>
		AIDC Form  or QR form 
Serial number		CU01<CCDDDDAAAAXXXXXX> 

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Information	Symbol	Text to accompany the symbol
LOT number		<i>Defined by production site</i>
Catalogue number		CU01CCDDD

5.2 Example label

Fully populated


Legal manufacturer
City and country
www.website.xxx


Drug Brand name

5V  500 mA / USB-C

 Rx Only 

  IP22

FCC ID: 2A663-CU01
IC ID: 28707-CU01 HVIN: CU01

 YYYY/MM/DD

 CU01CCDDD

 CU01CCDDDAAXXXXXX

 123 456 789




Pre printed label





5V  500 mA / USB-C

 Rx Only 

  IP22

FCC ID: 2A663-CU01
IC ID: 28707-CU01 HVIN: CU01









