# DOSE
# Labelling and Packaging Specification

| Author, date | Signature | Clarification of signature |
|---|---|---|
| 2023-03-02 |  | Emma Widehäll |
| **Approved, date** | **Signature** | **Clarification of signature** |
| 2023-03-02 |  | Dean Minnock |

# CONTENTS

# 1 Introduction

## 1.1 Scope

This report describes the labelling and packaging, for DOSE.

## 1.2 Revision history

| *Version* | *Approved by* | *Approval date* | *Description* |
| --- | --- | --- | --- |
| 01 | | | First version |
| 02 | | | References corrected. Symbol for consulting IFU changed from the version in ISO 15223-1 to “the blue man”. |
| 03 | Dean Minnock | 2022-12-23 | Added FCC ID number |
| 04 | Dean Minnock | 2023-01-10 | Legal manufacturer address updated on labels.<br>Label position added (chapter 3.3) |
| 05 | Dean Minnock | 2023-02-23 | Updated layout for LBL02 (v05) with separate sticker. Details added on printing and label content. |
| 06 | | 2023-03-02 | Figures are updated with the V6 of the packaging label. Figure 3 is updated to include the printed label. |

## 1.3 Definitions

| *Term* | *Definition* |
| --- | --- |
| | |
| | |
| | |

## 1.4 References

[1] IZDOSE-LBL01 Device label
[2] IZDOSE-LBL02 Packaging label
[3] IZDOSE-PR-OTH-047 Packaging with print

# 2 Unique Label Identifier

The label issue shall be present on the label according to ISO 20417; paragraph 6.1.4 d). The unique label identifier is a combination of the identification number for the device – IZDOSE – the label identifier – LBLXX – and the version code – XX, starting at 01.

For DOSE there are two different labels, the device label and the packaging label. Below are the different unique label identifiers for DOSE labels presented. XX represents the version.

*Table 1: Overview of Unique label identifiers for DOSE labels.*

| ***Label type*** | ***Unique label identifier*** |
|---|---|
| Device label | IZDOSE-LBL01-XX |
| Packaging label | IZDOSE-LBL02-XX |

# 3 Markings on the outside of the device – Device label

## 3.1 Elements on Device label

The elements to be used on the outside of the device, i.e. on the device label, are presented in Table 2 below.

*Table 2 Elements to include on the outside of the device.*

| ***Element*** | ***ISO 15223-1*** | ***Requirement*** | ***Comment*** |
|---|---|---|---|
|  | 5.1.1 | IEC 60601-1, Clause 7.2.2 | Manufacturer info (name, trademark, and address) |
|  | 5.1.6 | IEC 60601-1, Clause 7.2.2 | Type Reference or Model Version |
|  | - | IEC 60601-1, Clause 7.2.2 | Serial number. May be removed if lot or batch identifier is used. |
|  | - | IEC 60601-1, Clause 7.2.2 | The date of manufacture |
|  | - | IEC 60601-1, Clause 7.2.3 | Indicates the need for the user to consult the instructions for use.<br>To be accompanied with URL for e-IFU. |
|  | | IEC 60601-1, Clause 7.2.6, 7.2.7 | The RATED supply voltage, the nature of supply |
| FCC ID | - | 47 CFR on FCC | Legal requirement in the US market |

| ***Element*** | ***ISO 15223-1*** | ***Requirement*** | ***Comment*** |
|---|---|---|---|
|  | - | ISO 20417, Clause 6.5.2 | WEEE, safe disposal information |
| GTIN | - | | Global trade item number |
|  | - | | BLE ID |
|  | - | | Legal requirement on the EU market |
| IP 22 | - | IEC 60601-1, Clause 7.2.9 | IP classification |

## 3.2 Device label size and layout

The measurements of the device label [1] is 48,3 mm wide and 8,5 mm high.

The device label, IZDOSE-LBL01 has a layout according to Figure 1.

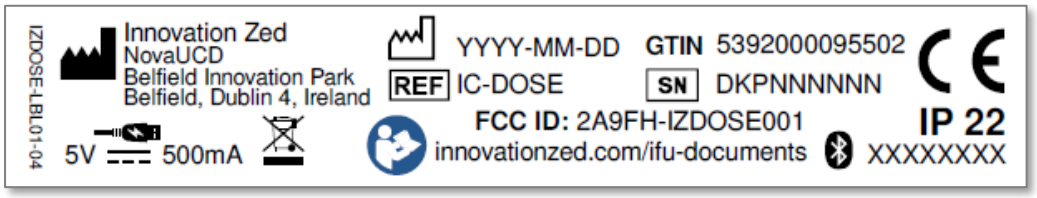


*Figure 1: Label IZDOSE-LBL01-04*

Some of the elements on the label are different depending on when the device is produced and specific device characteristics. These unique items are highlighted with yellow in Figure 2.

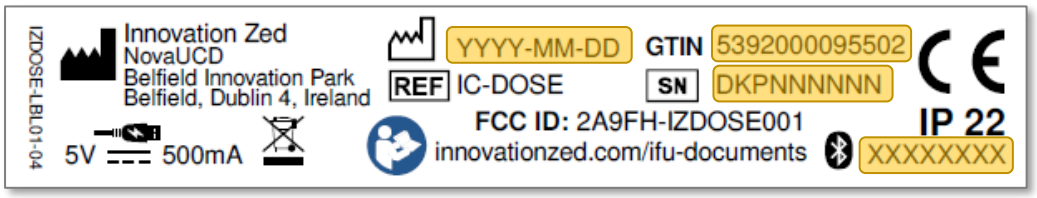


*Figure 2: Unique items, based on manufacturing date and device characteristics.*

## 3.3 Label position

The label is a sticker, fastened directly to the Dose device, with position and orientation according to Figure 3.

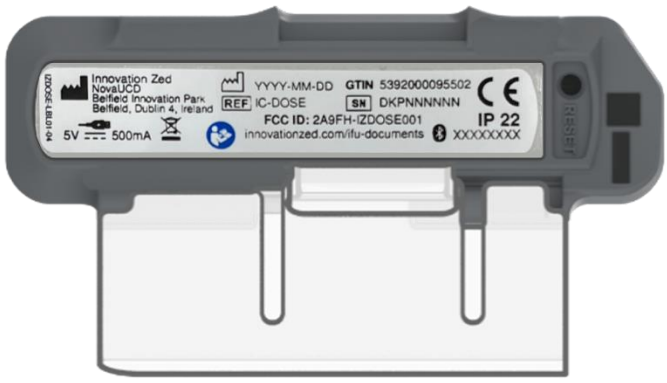


*Figure 3: Position of the label on the device.*

# 4 Information on the Packaging

The information elements to be established are presented below. In Section 4.3, an example of how the information may be incorporated in the label is shown.

## 4.1 Translations

Today there are no requirements on translations for the Dose device labels. However, if the device in the future becomes a Medical Device on the European market, all text strings on the label will require translations to local languages (according to GSPR 23.2b).

## 4.2 Elements on Packaging label

The elements to be used on the label are presented in Table 3 below.

*Table 3 Elements to include on the label.*

| ***Element*** | ***ISO 15223-1*** | ***Requirement*** | ***Comment*** |
|---|---|---|---|
|  | 5.1.1 | ISO 20417, Clause 6.5.1 | Manufacturer info (name and address) |
|  | 5.1.3 | ISO 20417, Clause 6.5.1 | Indicates the date when the device was manufactured |
|  | 5.1.5 | ISO 20417, Clause 6.5.1 | Indicates the manufacturer's batch code so that the batch or lot can be identified |
|  | 5.1.6 | ISO 20417, Clause 6.5.1 | Indicates the manufacturer's Catalogue number so that the device can be identified |
|  | 5.1.7 | ISO 20417, Clause 6.5.1 | Indicates the manufacturer's serial number so that a specific device can be identified |

| ***Element*** | ***ISO 15223-1*** | ***Requirement*** | ***Comment*** |
|---|---|---|---|
|  | 5.2.8 | IZDOSE-RMF-010 | If the packaging is damaged, the manufacturer cannot ensure the full function of the device. |
|  | 5.3.2 | ISO 20417, Clause 6.5.3 | Indicates a device that needs protection from sunlight |
|  | 5.3.4 | ISO 20417, Clause 6.5.3 | Indicates a device that needs to be protected from moisture |
|  | 5.3.7 | ISO 20417, Clause 6.5.3 | Indicates the temperature limits to which the device can be safely exposed |
|  | 5.3.8 | ISO 20417, Clause 6.5.3 | Indicates the range of humidity to which the device can be safely exposed |
|  | - | ISO 20417, Clause 6.1.5 | Indicates the need for the user to consult the instructions for use.<br>To be accompanied with URL for e-IFU. |
|  | - | ISO 20417, Clause 6.5.2 | WEEE, safe disposal information |
| Unique Device Identifier (UDI) | - | ISO 20417, Clause 6.5.1 | Identifies the UDI carrier, including the AIDC and human readable information. |
| Necessary contraindications | - | ISO 20417, Clause 6.5.2 | |
| Details necessary to identify the medical device and its use. (statement of intended use) | - | ISO 20417, Clause 6.1.3 | |
| Commercial product name/ Name or trade name of the device | - | ISO 20417, Clause 6.1.3 and 6.5.1 | |
| CE | - | | Legal requirement on the EU market |

## 4.3 Packaging label size and layout

Some items on the label will be specific for each device (e.g. manufacturing date), and to handle this within production, the packaging label is created in two steps. One step is to print the consistent information on the packaging using the layout file Packaging with Print [3] and the second step is to print the device specific information on a small sticker using the layout file Packaging Label [2], and this sticker will be added to the package afterwards, see Figure 4. For a correct placement of the sticker, a grey area is printed in the first step, which the sticker should be added on top of, covering it entirely, see Figure 5.

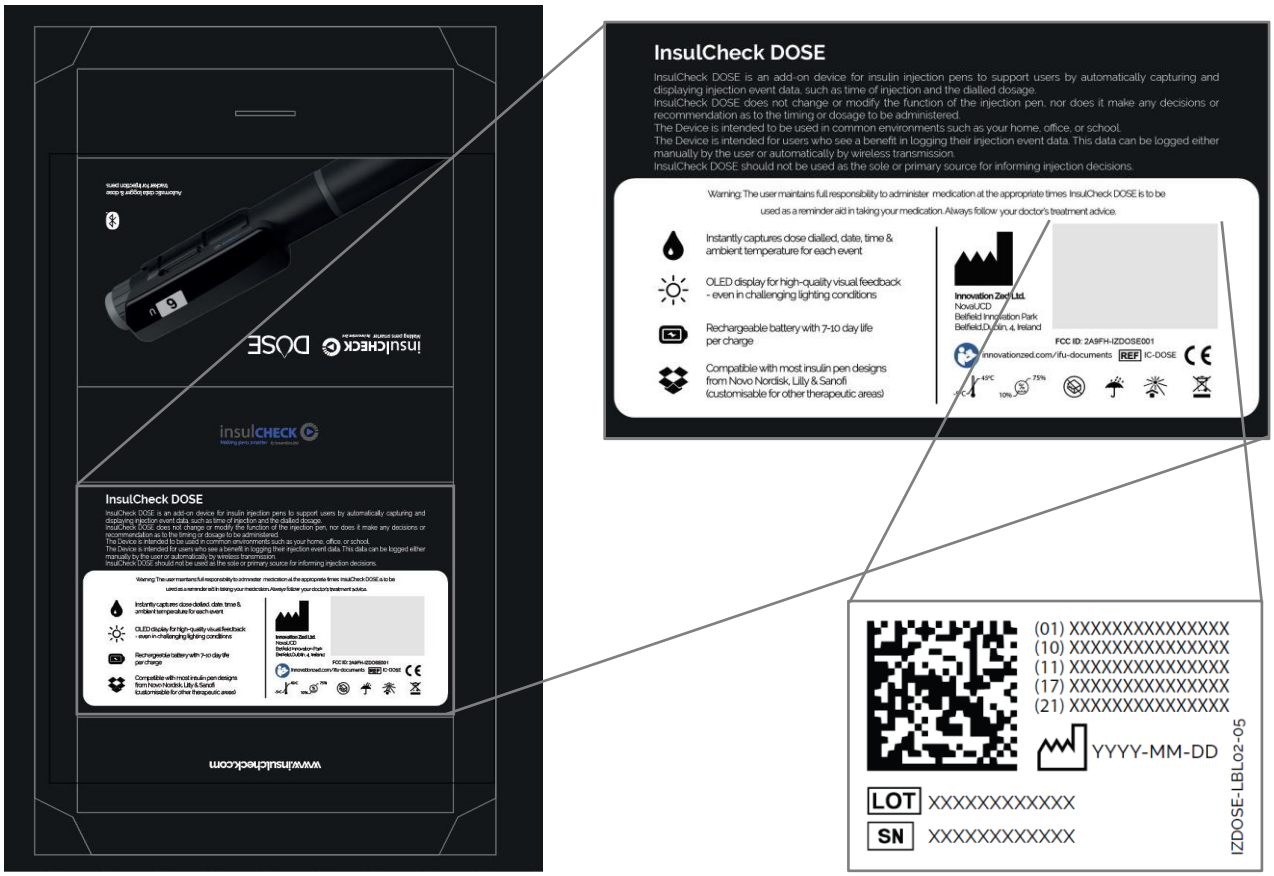


*Figure 4: The packaging print with the packaging label integrated. Some information is printed on a separate sticker.*

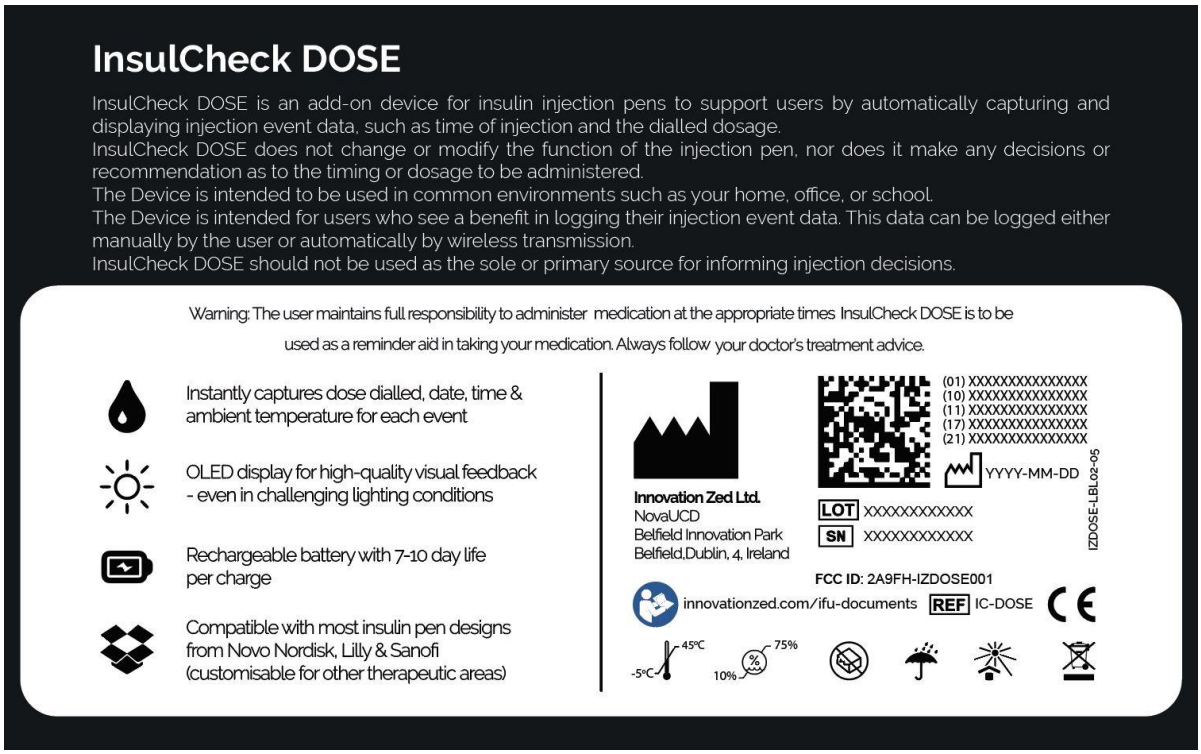


*Figure 5: The packaging print after the sticker is added on top of the grey area*

The separate sticker, IZDOSE-LBL02, contains the fields with date and device specific information. This date and device specific information is explained in Figure 6.

The size of IZDOSE-LBL02 is 46x30 mm, and it is positioned on the packaging according to Figure 4.

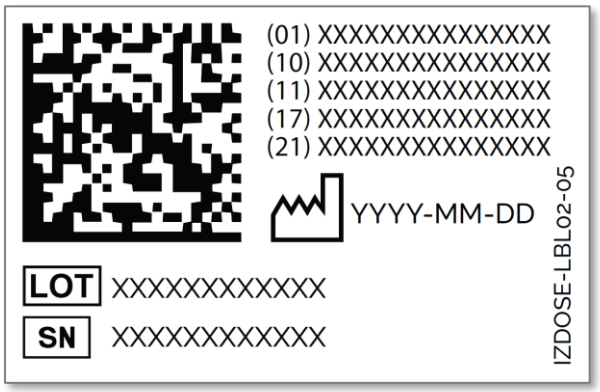


*Figure 6: Date and device specifics on the packaging label.*

***(01) GTIN***

- NovoPen5: 5391532050133
- FlexTouch: 5391532050140
- KwikPen: 5391532050164
- SoloStar: 5391532050157

***(10) Batch or lot number:*** *Up To 20 Char, Num & Letters, (follow same scheme as CONNECT): This is repeated in the LOT field.*

a) NP5-YYMM-N
b) SS-YYMM-N
c) FT-YYMM-N
d) KP-YYMM-N

***(11) Production date:*** *6 Char must follow format YYMMDD. Repeated next to symbol for manufacturing.*

***(17) Expiration date:*** *6 Char must follow format YYMMDD (1 year from manufacturing date to indicate battery "shelf life")*

***(21) Serial number:*** *Up To 20 Char, Num & Letters This repeated in the SN field*

# 5 Packaging details

The packaging for DOSE is a printed cardboard box according to Packaging with print [3]. This file also specifies dimensions of the packaging.

The Packaging label is included in the box print as described in Section 4.