

BIOCOP variation declaration concerning the differences between: MALLYA / EMBODY models

We,

BIOCOP PRODUCTION
ZI de Lavaur – La Bechade
63500 ISSOIRE, France

A company duly registered and organized under the laws of France, guarantee and declare, under our sole responsibility, that the device:

Device trademark: **MALLYA / EMBODY**

is declined into several models.

Each model has been specifically designed to adapt an insulin pens platform available on the market:

| Device designed for : | Models designation : | Models reference : | Picture |
|--|----------------------|-----------------------|---|
| MALLYA® DESIGNED FOR KWIKPEN® ELI LILLY | MALLYA for KWIKPEN | MALLYA / 0273694-KWKP |  |
| MALLYA® DESIGNED FOR FLEXPEN® NOVO NORDISK | MALLYA for FLEXPEN | MALLYA / 0273778-FLXP |  |
| MALLYA® DESIGNED FOR SOLOSTAR® SANOFI | MALLYA for SOLOSTAR | MALLYA / 0273777-SLST |  |
| EMBODY® DESIGNED FOR SOLOSTAR® SANOFI | EMBODY* for SOLOSTAR | EMBODY / 0273790-SLST |  |

*Only the device trademark is different between MALLYA and EMBODY for SOLOSTAR. The name "EMBODY" has specifically been created for marketing purpose.

The MALLYA / EMBODY variants are almost similar:

- they have the **same layout**,
- they have the **same hardware**. They include the **same electronic board and battery** (in the base):

The MALLYA / EMBODY models have:

the same schematic diagram, PCB layout and RF spec.

- they are made of materials from the same identified list

Overall, the difference between each model is only slight dimensional:

| ELEMENT | WEIGHT | INSULIN PEN | SIZE |
|---------------------|----------|-----------------------------------|---|
| Mallya base | 0.016 kg | KWIKPEN® FLEXPEN® SOLOSTAR® | (60.8x28.9x21.3) mm (60.8x26.9x21.3) mm |
| Mallya button | 0.006 kg | KWIKPEN® FLEXPEN® SOLOSTAR® | (11.6 x Ø22) mm (26.3 x Ø19.3) mm (24.4 x Ø20) mm |
| Mallya total weight | 0.022 kg | - | - |

- The MALLYA/ EMBODY base window is different between each MALLYA/ EMBODY model to specifically adapt to the specific injector pen dose window.

- The MALLYA/ EMBODY button shape vary to specifically adapt to the pen injection button it is affixed on.

Issoire, January 29, 2021

Name: Alexia GARIN

Title: Regulatory Affairs VP

Signature :

