

## BIOCORP variation declaration concerning the differences between: MALLYA / EMBODY models





We,

BIOCORP PRODUCTION  
ZI de Lavour – 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:

<i>Device designed for :</i>	<i>Models designation :</i>	<i>Models reference :</i>	<i>Picture</i>
<b>MALLYA®</b> DESIGNED FOR <b>KWIKPEN®</b> ELI LILLY	MALLYA for KWIKPEN	MALLYA / 0273694-KWKP	
<b>MALLYA®</b> DESIGNED FOR <b>FLEXPEN®</b> NOVO NORDISK	MALLYA for FLEXPEN	MALLYA / 0273778-FLXP	
<b>MALLYA®</b> DESIGNED FOR <b>SOLOSTAR®</b> SANOFI	MALLYA for SOLOSTAR	MALLYA / 0273777-SLST	
<b>EMBODY®</b> DESIGNED FOR <b>SOLOSTAR®</b> 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 <sup>®</sup>	(60.8x28.9x21.3) mm
		FLEXPEN <sup>®</sup>	(60.8x26.9x21.3) mm
		SOLOSTAR <sup>®</sup>	
Mallya button	0.006 kg	KWIKPEN <sup>®</sup>	(11.6 x Ø22) mm
		FLEXPEN <sup>®</sup>	(26.3 x Ø19.3) mm
		SOLOSTAR <sup>®</sup>	(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 :

