DUKADA ApS

Declaration of Conformity

We,

DUKADA ApS, Diplomvej 381, 2800 Kgs. Lyngby, Denmark,

hereby declare on our own responsibility as the manufacturer, that the following Medical Devices with variants of the product and the following intended use:

for use as an accessory to medical delivery systems - designed as pens (i.a. insulin pens) - for alleviating the use of the pen

meet all the requirements of the following Regulations and Directives

- Regulation EU/2017/745 for medical devices with amendments (MDR)
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2)

Name of device	Description	Classification according to MDD	MD Product code
Dukada Trio	Main cap with two openings, a foldable finger grip, light and time span indicator, top cap without any feature.	The product is a Class I product - according to rule 13 of Annex VIII of the MDR	MD 0100 General non-active, non-implantable medical device.

The product comes in the following versions:

Name of device	Description	UDI-DI	MD Product code
Dukada Trio for Novo FlexPen	This version of the above-mentioned product fits the Novo FlexPen	EAN barcode 5700002056900	MD 0100

Name of device	Description	UDI-DI	MD Product code
Dukada Trio for Sanofi SoloStar	This version of the above-mentioned product fits the Sanofi SoloStar Pen	EAN barcode 5700002056917	MD 0100

Route of conformity for Dukada Trio and variants of the product
Annex I, II and III of the MDR

Applicable harmonized standards and normative documents
See the Regulatory Plan for the product.

27 April 2021

Jakob Dahl Thomsen
Director of DUKADA ApS (subsidiary name In.Tool ApS)
CVR. 34589844
Diplomvej 381
DK-2800 Kgs. Lyngby
Denmark