

**MDRDoC Reference:** MDRDOC50780**Legal Manufacturer****BK Medical ApS, Mileparken 34, 2730 Herlev, Denmark****SRN: DK-MF-000006447****Notified Body:** N/A**Identification number:** N/A**Certificates:** N/A**Compliance (Conformity assessment) Procedure:**

Technical Documentation set out in Annexes II and III of Regulation (EU) 2017/745

**Risk class in accordance with the rules set out in Annex VIII:**

Class I device

| Product / Group Name   | Trade Name / Product Reference | Basic UDI-DI   | Risk Classification* |
|------------------------|--------------------------------|----------------|----------------------|
| Reusable Needle Guides | UA1239                         | 570491601001AD | I                    |
| Reusable Needle Guides | UA1250                         | 570491601001AD | I                    |
| Reusable Needle Guides | UA1251                         | 570491601001AD | I                    |

**\*The Class I products listed in this table are not covered by Notified body Certificate**

“We hereby declare that the above-mentioned product/s fulfill the requirements specified in the Medical Device Regulation (EU) 2017/745.

This EU declaration of conformity is issued under the sole responsibility of the BK Medical.

Herlev, date: 2021.06.18

BK Medical:

Signature:

Name and Position: Susanne Faarbæk – *Sr Dir Quality Assurance & Reg Affairs*