# *EC Declaration of Conformity*

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|---|---|
| **Manufacturer Name:** | RefLab Aps |
| **Manufacturer Address:** | Ole Maaløes Vej 3, COBIS<br>2200 Copenhagen N<br>DK-Denmark |
| **SRN (Single Registration Number):** | DK-MF-000021844 |
| **Basic UDI-DI:** | 574400328SOFTWE5 |
| **Name of the Device(s):** | Software(501) ver 3.0-0612, Software (501) ver 4.0-0613, Software (500-1) ver 12-0612, Software(501-1) ver 13-0913 |
| **Catalogue number(s):** | v3.0-0612, v4.0-0613, v12-0612, v13-0913 |
| **Product code:** | W0201020282 |
| **Classification:** | IVDR, Class A |
| **Notified Body name:** | N/A |
| **Notified Body Address:** | N/A |
| **Notified Body Identification number:** | N/A |
| **Conformity assessment route:** | RefLab Aps uses the following procedures for the CE-labeling of their products according to the Regulation IVDR 2017/746:<br><br>Class A: EC conformity declaration according to Annex IV. |

This declaration of conformity is issued under the sole responsibility of RefLab Aps. We hereby declare that the in-vitro diagnostic medical device(s) specified above meet the provision of the Regulation (EU) IVDR 2017/746. This declaration is supported by the ISO 13485 Quality Management System approval issued by DQS. All supporting documentation is retained at the premises of the manufacturer.

**Signature:**

Lise Bo
Quality Manager

**Place and date (dd.mm.yyyy) of issue:**

Copenhagen, 20.05.2022