

EU Declaration of Conformity – Self-Assessment of PD-100

1. This EU Declaration of Conformity (DoC) applies to the product:

PD-100

Basic UDI-DI No. 57000022502PDRH

UDI-DI No. 05700002250209

2. PD-100 is manufactured by:

PRO Devices A/S

Gadeledsvej 27C

DK-3400 Hilleroed

Denmark

SRN no: DK-MF-000000962

3. This DoC is issued under the sole responsibility of the manufacturer PRO Devices A/S and the DoC is created as a self-assessment of conformity.

4. Object of the declaration is **PD-100**, a laboratory equipment that can support the Medical Laboratory Professionals in their daily work. PD-100 takes a photo and measures the inhibition zones for the Antimicrobial Susceptibility Testing (AST) using the Disc Diffusion Method. PD-100 is a manual equipment with no EUCAST warnings or diagnosis.



5. PD-100 equipment is classified as an In Vitro Diagnostic Device (IVD) – Class A.

6. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

Signed for and on behalf of **PRO Devices A/S**:

Hilleroed, 2024-05-15



Charlotte Enghave Fruergaard, CEO