# **EC** Certificate

#### mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

### in.vent Diagnostica GmbH Neuendorfstraße 17 16761 Hennigsdorf Germany

for the scope

Control material for the detection of the tumor marker PSA: In.QualiCheck PSA

has introduced and applies a

#### **Quality System**

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

## Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/EC

of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from<br/>Valid until2022-03-11<br/>2025-02-18Registration no.<br/>Report no.D1407800011<br/>P21-02007-222784<br/>2022-03-11

**Head of Certification Body** 





Internet: http://www.mdc-ce.de