

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**BioSure (UK) Limited
Unit 59 Hillgrove Business Park
EN9 2HB Nazeing, Essex
United Kingdom**

for the scope

**In vitro diagnostic rapid self-testing devices for
the detection of COVID-19 IgG Antibodies in human blood
BioSURE COVID-19 IgG Antibody Self Test (Catalogue # 92001CST)**

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	2021-04-09
Valid until	2024-05-26
Registration no.	D1474600002
Report no.	P20-01356-183359
Stuttgart	2021-04-09




Head of Certification Body



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