

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

sifin diagnostics gmbh
Berliner Allee 317-321
13088 Berlin
Germany

for the scope

**blood group test reagents, bedside cards Serafol[®],
kits and test reagents are used for blood grouping using
the automated blood grouping analysers
PK7200 and PK7300**

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	2022-05-16
Valid until	2025-05-26
Registration no.	D1058700053
Report no.	P22-00540-237063
Stuttgart	2022-05-16


Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-247.10.05