EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

Hain Lifescience GmbH
Hardwiesenstraße 1
72147 Nehren
Germany

for the scope

GenoQuick HLA-B27 Version 2.0 and FluoroType®HLA-B27,
assay for the biomolecular detection of the human HLA-B27 gene from whole blood for diagnosis of associated illnesses, especially Bechterew's disease;
GenoQuick CT and FluoroType® CT,
assay for the biomolecular detection of Chlamydia trachomatis from urine, ejaculate, swabs and synovial fluid (GenoQuick CT only)
FluoroType®CMV,
assay for the quantitative detection of Cytomegalovirus DNA from human EDTA plasma and urine samples
FluoroType® CMV HT VER 1.0,
assay for the automated quantification of Cytomegalovirus DNA from human EDTA plasma and urine samples

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	2019-06-18
Valid until	2021-02-09
Registration no.	D1050000022
Report no.	P19-00683-150023
Stuttgart	2019-06-18

Head of Certification Body

medical device certification mdc

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

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