

Certificate

mdc medical device certification GmbH
certifies that

Diatron MI Zrt.
Táblás street 39.
1097 Budapest
Hungary

for the scope

**Design and development, manufacturing, sales and service of
in-vitro diagnostic instruments, for analysis of serum,
plasma and formed elements in blood, which are used in clinical laboratories.**
Design and development, manufacturing and sale of in-vitro diagnostic reagents.

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from 2021-05-28
Valid until 2024-05-27
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Head of Certification Body



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