

# 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
Registration no.	D1459100003
Report no.	P20-02033-193608
Stuttgart	2021-05-14



Head of Certification Body

