For electronic distribution only
Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

Diatron MI Zrt.
Táblás street 39.
1097 Budapest
Hungary

the introduction and application of a

Quality management system according to EN ISO 13485

in 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 dedicated in-vitro diagnostic reagents.

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from	2024-05-28	Registration No.	D1459100005
Valid until	2027-05-27	Report No.	P24-00156-289896

Stuttgart, 2024-05-27

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00