QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-522-135-2004

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.

as a Certification Body with ID No. NAH-4-0096/2016 accredited by the National Accreditation Authority for management system certification certifies that the quality management system applied by

Newmars Technologies Kft. 1051 Budapest, Széchenyi tér 7. 1133 Budapest, Gogol utca 13. Hungary

to the exclusion of sub-clause 7.3 Design and development

meets the requirements of standard

EN ISO 13485:2016

in the field:

Manufacturing and distribution of LuViva Advanced Cervical Scan system, and distribution of Cervical guides (test tubes);

Contracted manufacturing and distribution of medOC VMC Compounding Systems, and distribution of accessories

Registry number of the related audit report: NE/1015/2020

This certificate is valid until 2023-04-28 supposed that the results of the regular yearly surveillance audits are satisfactory.

Issue: 2

First issued: 2020-04-29

Budapest, 2020-12-14





EMKI 2631

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft. neoEMKI National Medical Device Conformity Assessment and Certification LLC.

