QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-515-135-2002

The Directorate of Device Testing and Clinical Engineering (EMKI)

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

ULTRAGEL Hungary 2000 Kft. 1023 Budapest, Bécsi út 4. 1211 Budapest, Tekercselő utca 12. Hungary

to the exclusion of sub-clause 7.3 Design and development

meets the requirements of standard

EN ISO 13485:2016

in the field:

Production and distribution of medical gels, and distribution of medical devices

Registry number of the related audit report: 43-33834-2014

This certificate is valid until 2023-02-12 supposed that the results of the regular yearly surveillance audits are satisfactory.

Budapest, 2020-02-13



Head of EMKI



EMKI 2345

The authenticity and validity of the certificate are verifiable at EMKI.

