Dear Client,

Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) - replacing Directives 93/42 / EEC (MDD) on medical devices and 90/385 / EEC (AIMDD) on active implantable medical devices – was published in April 2017 and actually entered into force on 26 May 2017, originally with the facilitation of setting a 3 year-long transitional period for implementation.

This transitional period would have originally ended up on 26 May 2020, but due to the COVID19 epidemic, EU decision-makers postponed it until 26 May 2021.

From this date the MDR is fully applicable. According to MDR Article 120 (3), certificates issued in accordance with the Directives remain valid until their original expiry date, but not later than 26 May 2024. The validity of the certificates is subject to the condition that the certified device continues to comply with the requirements of the relevant directive and the manufacturer does not make any significant changes to its design or intended purpose.

As the above deadline expired, we would like to draw your attention to the following important changes in our activities as a result of the provisions of Article 120 of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR):

The designation of NEOEMKI under Directive 93/42 / EEC has changed.

NEOEMKI will no longer accept any application for certification under Directive 93/42 / EEC (MDD) and will not be able to make any changes or alterations to the certificates issued and valid to date.

However, for clients with a valid certificate, NEOEMKI will continue to carry out its supervisory activities in full until 26 May 2024, both in terms of annual surveillance and unannounced audits, as well as examination of technical documentation and product design dossiers.

The designation status can be checked in the NANDO database at the following link: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13.

Any planned or implemented change on the manufacturers' products certified by NEOEMKI must be notified to us. Changes must be reviewed by the certification body. If it is established on the basis of the examination that the notified change is a substantial (significant) change affecting the design or intended purpose, the certificate must be withdrawn by NEOEMKI, so that further legal distribution of the device with the NEOEMKI certificate will no longer be possible. In such case, the device in question may be re-placed on the market after the successful completion of a new certification procedure in accordance with the requirements of the MDR.

The following document may give guidance in assessing significant changes:

MDCG 2020-3. Guidance on significant changes regarding the transitional provision under Article 120 of the MDR.

Since 26 of May 2021 in accordance with MDR Article 120 (3) NEOEMKI in the frame of its supervisory activities will monitor its certified product manufacturers' compliance with MDR requirements relating to post-market surveillance, market surveillance, vigilance and registration of economic operators and products.

Any non-conformities with these requirements will be considered as a serious non-compliance in all cases, and the certificate can only be maintained after the non-conformity has been fully corrected.

If no correction is made or cannot be accepted, NEOEMKI shall suspend the certificate after informing the competent authority.

In relation with MDR requirements relating to post-market surveillance, market surveillance, vigilance and registration of economic operators and products, NEOEMKI will primarily, but not exclusively, check the following:

Requirements relating to registration of economic operators and products

Relevant regulations: Article 15 of the MDR on the designation person responsible for regulatory (PRRC), MDR Articles 29-32, relevant parts of the Annex VI and the relevant MDCG guidelines. (primarily, but not limited to: MDCG 2019-4; MDCG 2019-5; MDCG 2019-7; MDCG 2021-1 Rev. 1)
Relevant quality management system requirements
• To compile and update the Summary of Safety and Clinical Performance (SSCP)
• Procedure for the designation and responsibilities of the responsible person (PRRC).
In the course of further inspections, NEOEMKI will consider any non-conformities in this area as serious.

Documentation relating to post-market surveillance and vigilance

- PMS, PMCF plans,
- PMS, PMCF, periodic device safety completed reports,
- trend reports (if applicable),
- Summary of Safety and Clinical Performance (SSCP).

Related quality management system requirements: Adequacy of post-market surveillance (PMS) and vigilance procedures, in particular

- • procedures for planning and evaluating the PMS, PMCF, updating the reports,
- • managing periodic device safety (PSUR) and trend reports,
- • managing the Summary of Safety and Clinical Performance (SSCP).

The PMS, PMCF plans will be checked by NEOEMKI during the next supervision. PMS, PMCF reports, periodic device safety and trend reports will be audited during inspections after May 26, 2022.
The SSCP must be verified and validated before the device is registered.

In relation with the above NEOEMKI will check primarily the fulfilment of the following requirements: MDR (Chapter VII) Articles 83-89 and Article 32 (SSCP), Annex III (post-market monitoring) and Annex XIV. Part B, the relevant MDCG guidelines (primarily, but not limited to: MDCG 2019-9; MDCG 2020-7; MDCG 2020-8).

In case of non-conformity or deficiency, the certificate can only be valid after the non-conformity has been completely corrected.

As some of the requirements listed above are a precondition for registration (eg. PRRC, SSCP), NEOEMKI hereby draws the attention of all customers to notify the certification body at least one month in advance and, if necessary, submit all related documents for checking and validation.

Budapest, 1st of June 2021