3R Indústria e Comércio Eireli
William R.C. Matteucci
Rua Ptolomeu, 390-São Paulo
SP – Zipe Code: 04762-040-Brazil

Our ref.:	In charge:	Place and date:
300/Bal/ 834	Ing. Tomáš Závišek	Zlín, 16th June 2021

Dear business partners,

In accordance with Article 120(3) of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (MDR) your company is enabled to place on the market latest until 26th May 2024 medical devices, that are covered by a valid EC certificate issued by a Notified body pursuant to Directive 93/42/EEC (MDD).

This possibility can be used only in case no changes have been made in product design and intended purpose, and the notified body that issued the certificate will continue to perform appropriate surveillance in respect of all of the applicable requirements relating to the certified devices.

However, the existing conditions need to be further complemented by the requirement of above mentioned Article 120(3) of the MDR specifying that the provisions of MDR relating to market surveillance (PMS – post-market surveillance, PMCF – post-market clinical follow-up), vigilance and registration of economic operators and of devices shall apply in place of the corresponding provisions in MDD.

In this context, we would like to draw your attention to the guidance MDCG 2021-1 (https://ec.europa.eu/health/md_sector/new_regulations/guidance_en), which provides a solution for the registration of manufacturers and medical devices at a time before the European database of medical devices EUDAMED is fully functional.

In order to carry out necessary surveillance regarding certificates issued by our company ITC we are attaching a proposal of a Framework Contract, which defines the duties and responsibilities of both parties, i.e. ITC and your company.

If you intend to take advantage of the transitional period for certified medical devices, please sign the contract and return a signed copy back to ITC.

We are looking forward to future cooperation.

Yours sincerely,

Tomáš Závišek
Head of Medical Device Certification Department

INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a.s. 763 02 ZLÍN 38

Enclosure:
2x Framework Contract No. 36001 on Surveillance Audits in transition period

Digitally signed by Jighiri Tatiana
Date: 2022.07.11 13:49:30 EEST
Reason: MoldSign Signature
Location: Moldova