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

Our ref.:
300/Bal/ 834

In charge:
Ing. Tomáš Závišek

Place and date:
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

Sao Paulo, May 11, 2022

D E C L A R A T I O N

We at 3R Indústria e Comércio Eireli declare for all due purposes that the CE Mark Certificate N° 160577 QS/NB valid on 2021-12-16 **can be marketed until May 26, 2024.**

The date of application of the Medical Device Regulation (MDR) is May 26, 2021, which means that compliance is mandatory to be able to place Medical Devices on the European market from this date, as per the Medical Device Regulation (EU) 2017/ 745 - **MDR Article 120 - Transitory Provisions:**

1. As of 26 May 2020, any publication of a notification concerning a notified body in accordance with Directives 90/385/EEC and 93/42/EEC is considered void.

2. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC before 25 May 2017 remain valid until the end of the period indicated on the certificate, with the exception of certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC, which become void no later than 27 May 2022. Certificates issued by notified bodies in accordance with Directives 90/ 385/EEC and 93/42/EEC from 25 May 2017 remain valid until the end of the period indicated on the certificate, which cannot exceed five years from its issue. However, they become void no later than May 27, 2024.

3. By way of derogation from Article 5 of this Regulation, a device bearing a certificate which has been issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid pursuant to paragraph 2 of this article, may only be placed on the market or put into service provided that, as of the date of application of this Regulation, it continues to comply with the provisions of one of those directives, and provided that the design and intended purpose have not been altered to such an extent. important. However, the requirements of this Regulation on post-market monitoring, market surveillance, surveillance and registration of economic operators and devices apply instead of the corresponding requirements of those Directives. Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph remains responsible for appropriate follow-up with regard to all applicable requirements in respect of all devices it has certified.

4. Devices legally placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC before 26 May 2020 and devices placed on the market after 26 May 2020 under a certificate, as referred to in paragraph 2 of this article, may continue to be made available on the market or to enter into service until 27 May 2025.

5. By way of derogation from the provisions of Directives 90/385/EEC and 93/42/EEC, devices that comply with the provisions of this Regulation may be placed on the market before 26 May 2020.

6. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies that comply with the provisions of this Regulation may be designated and notified before 26 May 2020. are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures set out in this Regulation and issue certified pursuant to this Regulation before 26 May 2020. 5.5.2017 EN Official Journal of the European Union L 117/89

7. With regard to devices subject to the consultation procedure provided for in Article 54, paragraph 5 of this Article shall apply provided that the necessary appointments to the MDCG and the panels of experts have been made.

3R Indústria e Comércio Eireli
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CNPJ: 02.543.673/0001-13

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Fone: (+55 11) 5525-0590

8. By way of derogation from Article 10a and Article 10b(1)(a) of Directive 90/385/EEC, as well as Article 14(1) and (2) and Article 14a(1)(a) and (b) of Directive 93/42/EEC, manufacturers, authorized representatives, importers and notified bodies that, during the period commencing on the last of the dates referred to in Article 123 .o(3)(d) and which expires 18 months later, comply with Article 29(4) and Article 56(5) of this Regulation, comply with laws and regulations adopted by the Member States in accordance, respectively, with Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC and, respectively, with the Article 10b(1)(a) of Directive 90/385/EEC or Article 14a(1)(a) and (b) of Directive 93/42/EEC, as specified in Decision 2010/ 227/EU.

We conclude that as per the regulation the current Validity of issued MDD certificates will be valid until the original expiration date **or May 26, 2024. We confirm that compliance is being maintained, elements of the MDR are being met and the Notified body is being carried out as surveillance activities.**

This means that we can continue to place MDD certified devices on the market until May 26, 2024, assuming they continue to maintain valid certifications. We state that after May 26, 2020 no significant changes have been made to MDD certified devices.

Migration from MDD certified devices to MDR is often seen as a requirements revision, but in reality, it is a new regulation. We are waiting for our Certification Body to go through the approval process so that we can apply for the certification process for the MDR.

Cátia Silva

3R Indústria e Comércio Eireli
Cátia Silva / Regulatory Affairs

EC Certificate - Full Quality Assurance System
No. 16 0577 QS/NB

The quality system of manufacturer

3R Industria e Comércio Eireli

Rua Ptolomeu, 290 – São Paulo / SP, Zip Code: 04762-040 – Brazil

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Dental Burs

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2020-06-30
Valid until: 2021-12-15
First Issued: 2016-12-16
Revision: c

São Paulo, 2018/January/31st

Dear Amanda Livingston,

My name is Wiliam Matteucci, director of 3R INDUSTRIA E COMERCIO LTDA **FDA REG# 3002820615 and OO# 9052649,** and this letter is to authorize FDA to send us the login and password information to our account.

Mr. Alvaro Vasquez is no longer cooperating into providing this information and I would like to become the new account holder. I would like also to indicate a new U.S. Agent.

If you need any additional information please contact me at william@3r.ind.br or (55-11) 5525-0590

Sincerely

William R. C. Matteucci
Diretor / Director

02.543.673/0001-13
3R - INDUSTRIA E COMÉRCIO LTDA - EPP
Rua Ptolomeu, 290
Socorro - CEP: 04762-040
São Paulo-SP

3R INDÚSTRIA E COMÉRCIO LTDA.
ADDRESS: PTOLOMEU, 290 – CEP 04762-040
SÃO PAULO – SP – BRAZIL,

Management Systems Certification Body
Institute for Testing and Certification, Inc.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
www.itczlin.cz

CERTIFICATE

No. 22 0002 SJ

We confirm on the basis of a performed audit that company

3R Indústria e Comércio Eireli.

Rua Ptolomeu, 290 – Socorro – São Paulo (SP) – 04762-040 – Brazil
Company Reg. No.: 02.543.673/0001-13

has implemented and documented a functional quality management system in compliance with the requirements of the standard

EN ISO 13485:2016

Covering the following activities:

Design and development, manufacture, sales and post-sales of diamond burs, dental device and dental instruments, sterile and non-sterile.

The Certificate is issued on the basis of the results mentioned in Audit Report No. 233405007/2021. The Certificate validity is conditioned by positive results of surveillance audits, which the certified company committed to undergo.
During use of the Certificate the Certificate Holder undertakes to follow the Rules of Use of the Certificate. This document is publicly available on www.itczlin.cz

S 3002

Date of Issue: 07. 01. 2022
Valid until: 06. 01. 2025

Date of the first certification awarding: 14. 03. 2016

Ing. Pavel Vaněk
Head of Certification Body