Business Stream Products
Certification department

TÜVRheinland®
LGA

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Cologne, 31 July 2023

To whom it may concern:

This cover letter relates to the “Technical Cooperation Programme on Exchange of Medical Device Quality Management System Regulation and ISO 13485 Audit Reports between EU MDR/IVDR Notified Body Partners and R.O.C. TFDA Authorized Medical Device QMS Auditing Organizations” (TCP III).

The Certification Body of TÜV Rheinland LGA Products GmbH confirms that the attached audit report # 1133642-40 Rev.01, dated 2023-07-13, is accurate and relating to the most recent re-certification audit performed in the company

Cavex Holland BV
Fustweg 5, 2031 CJ Haarlem, Netherlands
e-mail: dental@cavex.nl

for the Legal Manufacturer (as defined in the European regulation) Cavex Holland BV, Fustweg 5, 2031 CJ Haarlem, Netherlands, e-mail: dental@cavex.nl

For recognition of the TÜV Rheinland LGA Products GmbH certificate SX 1710455-1 according to EN ISO 13485:2016 by the Taiwan Food and Drug Administration (TFDA), this cover letter together with copies of the certificate, copies of the related audit report as well as the audit plan and the signed nonconformity reports need to be forwarded to the TFDA.

A “Certificate of Free Sale” issued by the relevant Competent Authority is additionally to be provided.

Sincerely

Digital unterschrieben
von Ute Frenkert
Datum: 2023.07.31
17:31:53 +02'00'

Certification department

TÜV Rheinland LGA Products GmbH

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