Business Stream Products
Certification department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH * 51105 Cologne * Am Grauen Stein 29 * Germany

Cavex Holland BV
Mr. Van der Bor
Fustweg 5
2031 CJ Haarlem
The Netherlands

Your correspondence
Fabian Bley

Tel. +49 221/806-4300
Fax +49 221/806-1601
Mail medical-products
@de.tuv.com

Cologne, 5 August 2020

To whom it may concern:

This cover letter relates to the "Technical Cooperation Programme on exchange of Medical Device GMP and ISO 13485 Audit Reports between EU AIMD/MDD/IVDD Notified Body Partners and R.O.C. TFDA Authorized Medical Device GMP Auditing Organizations".

The Certification Body of TÜV Rheinland LGA Products GmbH confirms, that the attached audit report # 3316045 90 is accurate and relating to the most recent re-certification audit performed in the company

Cavex Holland BV, Fustweg 5, 2031 CJ Haarlem, The Netherlands
Phone: +31 (0) 235307700, Fax: +31 (0) 235356482, E-Mail: dental@cavex.nl

for the Legal Manufacturer (as defined in the European regulation)

Cavex Holland BV, Fustweg 5, 2031 CJ Haarlem, The Netherlands,
Phone: +31 (0) 235307700, Fax: +31 (0) 235356482, 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 of the Department of Health (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

Dipl.-Ing. U. Frenkert

Certification department

TÜV Rheinland LGA Products GmbH

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nuremberg
Germany

Phone +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety