

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

Contact

**ROLAND CONSULT Stasche & Finger GmbH**  
Herr Joachim Finger  
Heidelberger Str. 7  
14772 Brandenburg  
Germany

Tel. +49 221/806-4300  
Fax +49 221/806-1601  
Mail [medical-products@de.tuv.com](mailto:medical-products@de.tuv.com)

Cologne, 1 June 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 # 1101678-40 Rev. 1, dated 2023-03-02, is accurate and relating to the most recent re-certification performed in the company

**ROLAND CONSULT Stasche & Finger GmbH**  
**Heidelberger Straße 7, 14772 Brandenburg, Germany**  
**phone: 0049 3381 890 1034, e-mail: [info@roland-consult.de](mailto:info@roland-consult.de)**

for the Legal Manufacturer (as defined in the European regulation) ROLAND CONSULT Stasche & Finger GmbH, Heidelberger Straße 7, 14772 Brandenburg, Germany, phone: 0049 3381 890 1034, e-mail: [info@roland-consult.de](mailto:info@roland-consult.de).

For recognition of the TÜV Rheinland LGA Products GmbH certificate SX 1622966-1 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

  


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](mailto:service@de.tuv.com)  
[www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Nuremberg HRB 26013  
VAT No.: DE811835490

Chairman of the  
Supervisory Board

Dr.-Ing. Michael Fübi