

**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60138765 0001

**Report No.:** 15069263 009

**Manufacturer:** TIANJIN GAPADENT CO., LTD  
NO.24 FengZe Road, (ZhangJiaWo Industrial Area)  
Automotive Industrial Area  
XiQing District  
300380 Tianjin  
P.R. China

**Products:** Sterile Absorbent Paper Points and Gutta Percha Points

TÜVRheinland®

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2020-12-31

**Date:** 2020-12-31

**Notified Body**

Jing Zhang



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



**TIANJIN GAPADENT CO., LTD.**  
**NO. 24 FengZe Road, (ZhangJiaWo Industrial Area) Automotive Industrial Area XiQing District**  
**300380 Tianjin,**  
**P.R. China**

2024/05/13

**Confirmation Letter Reference: CLNB1639 - CN/TSN/286008**

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

**TIANJIN GAPADENT CO., LTD.**  
**NO. 24 FengZe Road, (ZhangJiaWo Industrial Area) Automotive Industrial Area XiQing District**  
**300380 Tianjin,**  
**P.R. China**  
**SRN Number: CN-MF-000030044**

**Authorized Representative:**  
**Shanghai International Holding Corp. GmbH(Europe)**  
**Eiffestrasse 80, 20537 Hamburg,**  
**Germany**  
**SRN Number: DE-AR-000000001**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive

93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26<sup>th</sup> May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26<sup>th</sup> May 2026 for Class III custom-made implantable devices
- 31<sup>st</sup> December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31<sup>st</sup> December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31<sup>st</sup> December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV NB1639,



Pp[Sean Kelly]  
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Global Medical Device Certification Manager  
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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	MDD Device name (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile Absorbent Paper Points Basic UDI-DI: 697015700GAPAPPCT	Class IIa	N/A	N/A	Certificate DD601387650001 NB0197
Gutta Percha Points Basic UDI-DI: 697015700GAPAGPBY	Class IIa	N/A	N/A	Certificate DD601387650001 NB0197

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/13	Version:1	Initial issue