



Applimed SA
Z.I. Route de Pra de Plan Nr.1
1618 Châtel-St-Denis
Switzerland

Date: 21.06.2024

Confirmation Letter

To whom it may concern,

We hereby confirm 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 from the following manufacturer, under the framework of (EU) 2017/745 and Regulation (EU) 2023/607.

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Switzerland

SRN Number: Not yet Available

This letter confirms that the manufacturer's MDD certificate benefit from the extension period, provided the conditions set out in Article 120(3c), points (a) to (c), are fulfilled.

Received application is covering the following device:

- Class IIa sterile single use surgical instruments:
Aspiration Cannula, Curette, Forceps, Hooks, Irrigation Cannula, Probe,
Retractors, Scissors, Tweezers

- Class Is devices:
Sterile single use applicators for wound care & Sterile single use compresses
Sterile curettes, Sterile forceps, Sterile tweezers, Sterile speculum, Sterile ENT
Hooks and retractors
Sterile single use instruments used as accessories (Backhaus Towel Clamp,
Lister Scissors, Nail Scissors, Scissors, Tweezers, Blade Holder)
Sterile single use tongue depressor, Sterile single use surgical drapes, Sterile
procedure packs

According to Regulation 2023/607 this MDD certificate can be extended till 31 December 2028 if a contract is signed in between SGS Belgium NV and Applimed SA before 26 September 2024.



In parallel of the MDR designation process, Applimed has also apply for renewal of their ISO13485 certificate with SGS UK under UKAS accreditation for the following scope:

“Design, development, manufacture and sales of sterile and non-sterile single use medical devices dedicated to wound care including applicators, compress, cotton, wound irrigation cannulae, aspiration cannulae, wound care instruments, wound care sets, surgical instruments, surgical sets and procedure pack.

Distribution of sterile and non-sterile surgical devices, sterile active surgical devices, non-absorbable surgical sutures, sterile and non-sterile devices dedicated to patient care, and related accessories. Manufacture subcontract of sterile and non-sterile single use medical devices dedicated to wound care.

Subcontract of packaging for medical devices dedicated to wound care.”

Their certificate is under final review and shall be release in coming weeks.

Please do not hesitate to contact us if you require any further information.

Yours sincerely,

On behalf of the Notified Body SGS Belgium NV 1639,

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