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,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

CERTIFICATION

CONTRACT OFFER
Applimed SA

CONTRACT NUMBER: **HU/BUD/3882 (MDR+MDD+ISO 13485)**

overwriting the former HU/BUD/6802780 (MDD+ISO 13485) contract

EFFECTIVE DATE: **2024/9/20**

BE THE BENCHMARK

SGS

APPLIMED SA
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Phone: 021 / 948 92 74

Welcome to SGS,

We would like to thank you for giving us the opportunity to present our proposal for Medical Device Regulation (EU) 2017/745. The following document sets out our formal proposal of fees for certification needs. We are sure you expect us to be environmentally responsible, and so we have included only basic information about our services and the certification process with this proposal that is part of the Master service agreement signed in between your and SGS Belgium NV as Notified Body NB1639.

Please ensure that you have read and understood the MDR Conformity Assessment Process Explained documents which form part of this contract offer.

General Conditions for Certification Services | SGS
MDR Conformity Assessment Process Explained (sgs.com)
EU Medical Devices Regulations Information Center | SGS
MDR Contract Proposal Supplementary Documents

Further information about certification process can be provided upon request or for general information about our company and services please visit: www.sgs.com

Overview of SGS Medical Devices Services Medical Devices | SGS

Should you require any clarification, please do not hesitate to contact us. We look forward to being of service to your company.

I trust you will find our proposal meets your requirement. Please complete and return this document as soon as possible so that we can accommodate your preferred audit date.

Yours sincerely,

Sándor Olasz
Medical Device Auditor and Filed Sales Executive
sandor.olasz@sgs.com

Approved by:
András Kákonyi
Deputy Managing Director of SGS Hungária Kft.
andras.kakonyi@sgs.com

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CERTIFICATE REQUIREMENTS			
Company name	Applimed SA		
Invoicing address	Z.I. Rte de Pra de Plan Nr. 1 1618 Châtel-St-Denis Switzerland		
Contact person	Sasan Danechi	Position	Managing Director
Contact phone number	+41 21 948 92 74	Email	sasan@applimed.ch
Authorized Representative	na	SRN :	Not yet available.
Company Site	single site		
Relevant Subcontractors & Suppliers	submitted		

Standard(s)	MDR Annex 9 QMS
Accreditation body(s)	CE1639 (Accredited Body:SGS Belgium NV)
Total number of employees	50

Proposed scope(s) of certification

MDR (EU) 2017/745:
Class II.a devices:
Sterile Cleaning Surgical Instruments - Class IIa MDN1208
Intended use: metallic instrument used for cleaning/clearing/rinsing of the wound, inserting into the wound and indication/guidance/protection, during general surgery.
Non-active, non-implantable, surgically invasive, transient use.
Sterile single use surgical instruments including:
•Sterile curettes
•Sterile irrigation cannula
•Sterile aspiration cannula
•Sterile probes
Basic-UDI: 0764017844SInsCle0YA
Sterile Holding and Cutting Surgical Instruments - Class IIa MDN1208
Intended use: metallic instrument used for holding/cutting tissues, compresses, or other devices during general surgery. Non-active, non-implantable, surgically invasive, transient use.
Sterile single use surgical instruments including:
•Sterile forceps
•Sterile tweezers
•Sterile retractors
•Sterile hooks
•Sterile Forceps needle holder
•Sterile scissors
Basic-UDI: 0764017844SInsHol02L
Class I.s devices, where the technical assessment is limited to sterilization according to Article 52 of MDR:

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Class I.s devices MDN1204, MDN1208, MDN1214
Sterile single use applicators for wound care
Sterile single use compresses
Class I.s sterile single use wound care instruments including:
•Sterile curettes
•Sterile forceps
•Sterile tweezers
•Sterile speculum
•Sterile ENT Hooks and retractors
Class I.s sterile single use instruments used as accessories (Backhaus Towel Clamp, Lister Scissors, Nail Scissors, Scissors, Tweezers, Blade Holder)
Sterile single use tongue depressors
Sterile single use surgical drapes and
Sterile procedure packs having different intended uses depending on the contents.

MDR Codes	9003, Class I.s, Class IIa, MDN 1204 , MDN 1208 , MDN1214, MDS 1005, MDT 2001, MDT 2004, MDT 2008, MDT 2011 275, 511, 512, 143
Annual number of surveillance audits	1 Year
Total number of sites	1
Site address	Z.I. Rte de Pra de Plan Nr. 1 1618 Châtel-St-Denis Switzerland

Standard(s)	MDD 93/42/EEC Annex II. (excluding section 4)
Accreditation body(s)	CE1639 (Accredited Body:SGS Belgium NV)
Total number of employees	50

Proposed scope(s) of certification

MDD 93/42/EEC:
CH19/1051 - Annex II (excluding section 4)
Sterile single use surgical instruments including: •Sterile curettes •Sterile forceps •Sterile irrigation cannula •Sterile aspiration cannula •Sterile scissors •Sterile tweezers •Sterile retractors •Sterile hooks •Sterile probes •Sterile Forceps needle holder
Sterile and Non-sterile single use surgical instruments set including: •Surgery Sets •Ablation Suture Sets •Catheter Sets •Circumcision Sets
Sterile and Non-sterile single use care set including: •Care Sets with Syringe •Care Sets with Gloves •Badigeon Sets
Sterile and Non-sterile single use care set for patient preparation including: •Puncture Sets •Abscess Sets •Infiltration Sets •Gastroscopy Sets •IUD Sets •Childbirth Sets •Ingrown nail Sets •Medical Imaging Sets •Injection Sets •Diabetology Sets •Biopsy Sets
CH19/1050 - Annex V (sterility aspects only)
Sterile single use applicators for wound care
Sterile single use compresses

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Sterile single use surgical instruments set including Compress Sets Sterile single use care set including •Care Sets With Pad •Mouth Care Sets Sterile single use care set for patient preparation including •Urology Set •Vulvar Wash Sets •Wash Bladder Sets •Orthopaedic sets Sterile single use wound care instruments including: •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	
Standard(s)	ISO 13485:2016
Accreditation body(s)	UKAS (Accredited Body:SGS United Kingdom Limited)
Total number of employees	50
Proposed scope(s) of certification	23
ISO 13485 (BELAC / UKAS): 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 packs. 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	

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FEES			
CURRENCY: EUR (Excluding Expenses and VAT)			
Year	**Technical fees**	**Total EUR**	**Expected qty.**
2024	application fee	[redacted]	**once**
from 2026	annual MDR certificate maintenance fee - per MDR certificate, admin -technical fee, pro rata after certificate is issued, may vary annually based on NB guidance	[redacted]	**1 pc/ year**
from 2025	annual UKAS ISO 13485 certificate maintenance fee - technical fee, may be adjusted annually according to guidance from the NL	[redacted]	**1 pc/year**
	Confirmation Letter and/or Extension Letter	[redacted]	**1/year**
Year	**Initial audit**	**Total days**	**Total net. EUR**
2025	Stage 1		
	Stage 1 reporting		
	INI S1 Total	*3,0*	[redacted]
	Optional travel time per audior , if comes from abroad		[redacted]
2025	Stage 2 (MDT2008, MDS1005)		
	Stage 2 reporting		
	INI S2 Total	*10,0*	[redacted]
	Optional travel time per audior , if comes from abroad		[redacted]
	Optional MDD Surveillance		[redacted]
Year	**Technical Documentation Review**	**total days**	**Total net. EUR**
2025	*Class II.a devices MDS1005*	*11,5*	
	Class I.s devices MDS1005 (combined review)	*5,0*	
	Sterile procedure packs (combined review)	*1,5*	
	Clinical oversight (multiple II.a variants)	*2,5*	
	TDR total (indicative)	***20,5***	[redacted]
Year	**Surveillance audit**	**Total days**	**Total net. EUR**
2025, 2026, 2028, 2029	SUR audit		
	Report		
	SUR Total	*4,5*	[redacted]
	Optional travel time per audior , if comes from abroad		[redacted]

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	Optional MDD Surveillance		[redacted]

Year	ISO 13486 Renewal Audits	total days	Total net. EUR
2027	RAU audit + MDR SUR + testing		
	Report		
	RAU Total	7,5	[redacted]
	Optional travel time per audior , if comes from abroad		[redacted]
	Optional MDD Surveillance		[redacted]

Year	Technical Documentation Review	Total days	Total net. EUR
2026	*Class II.a MDS1005 (multiple variants)*	*11,5*	
	Clinical oversight	*2,5*	
	TDR total (indicative)	***14,0***	[redacted]

Year	Technical Documentation Review	Total days	Total net. EUR
2027	*Class II.a MDS1005*	*1,0*	
	Clinical oversight	*0,0*	
	TDR total (indicative)	***1,0***	[redacted]

Year	Technical Documentation Review	Total days	Total net. EUR
2028	*Class II.a MDS1005*	*1,0*	
	Clinical oversight	*0,0*	
	TDR total (indicative)	***1,0***	[redacted]

Year	Technical Documentation Review	Total days	Total net. EUR
2029	*Light review*	*1,0*	
	Clinical oversight	*0,0*	
	TDR total (indicative)	***1,0***	[redacted]

Year	Unannounced Audit	total days	Total net. EUR
n/a	Auditor 1		
	Travel		
	Auditor 2		
	Travel		
	UA Reporting		
	UA Total	6,5	[redacted]

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The fees shown are based on our current market rates. We will periodically review prices and apply increases in response to inflationary or other pressures, where necessary. SGS reserves the right to change any of the above conditions at any time. This proposal is valid for 60 days from date of issue.
Fees are normally charged after the services have been performed; unless stated otherwise and subject to a satisfactory credit check. We keep our fees clear and transparent and the only fees you may pay on top of those listed are VAT at the current rate. Charges may be made for cancellation of any agreed visit dates, when the cancellation is notified within 20 working days of the agreed date.

- If an indicative start date has been discussed, then this is reflected in the Example Date above, if not, then this is an example to illustrate when fees would be charged.
- In all cases the actual dates of the stages will be agreed with you by the scheduling team allocated to manage the next stage of your certification journey.

SGS operates a system of continuous certification. As part of this program it is not necessary to conduct a complete assessment. Rather, we conduct a recertification review which is more in depth than a surveillance visit and will ensure that we review all aspects of your system. The recertification activities must be carried out and nonconformities closed prior to the expiry of your current certificate.

This proposal has been prepared in accordance with the requirements of IAF (International Accreditation Forum) MD9 details of audit time determination and justification is available on request.

During MDD surveillance period NB1639 may request legacy TD assessment if it is justified, which can take maximum 5 days.

Change notifications

Every change notification will be charged on the following base: €370 /hr for Audit, €470/hr for Technical (Minimally 2 hrs)

Additional certificates

The prices always include one certificate in English. The price of an additional certificate in accordance with the original shall add cost in local currency. The price of a first bi-lingual certificate (English and requested language) shall be determined in accordance with the specifications.

Amendments

If an amendment of a previously issued certificate is needed, an additional administrative, registration and certification fee of add cost in local currency will be charged. All critical relevant subcontractors and crucial suppliers should have a valid and relevant EN ISO13485 certificate (or accepted equivalent certificate). Certification of outsourced activities has not been assessed at the Proposal stage, therefore if control of critical relevant subcontractors/crucial suppliers is found to be inadequate an audit may be required at additional cost.

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DECLARATION

On behalf of Applimed SA

By signing this document, we apply for assessment by SGS Hungária Kft. on behalf of SGS Belgium NV who are the Accredited Legal Entity for Notified Body CE1639 Accredited Certification and agree to abide by the SGS Codes of Practice, the Rules governing the use of the SGS certification mark and SGS General Conditions for certification services accessible at: Terms and Conditions | SGS as well as the conditions contained in this proposal.

If any of the details provided in this document change prior to your assessment, you must inform us in writing, as this may have an impact on this proposal and the assessment process.

We confirm that our attention was drawn to the clauses on limitations of liability and indemnification and jurisdiction. We also confirm that the above information provided to SGS for application process is accurate and agree to pay all costs as stated in this application.

Name	Sasan Daneshi	**Position**	Director
Signature		**Date**	24/09/2024

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