

	<p>TECHNICAL SPECIFICATIONS SHEET</p> <p>MEDICAL DEVICE</p>	<p><i>Review : 1.0</i></p> <p><i>Date : 02/10/20</i></p>
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1. Administrative information about the company	
1.1 Name : CM MEDICAL	
1.2 Address : 14, impasse de la fosse 81100 Castres France	Phone: (+33)5.63.72.04.64 Fax : e-mail : c.micheau@cm-medical.com Site internet : https://cm-medical.com/
1.3 Status: Manufacturer	

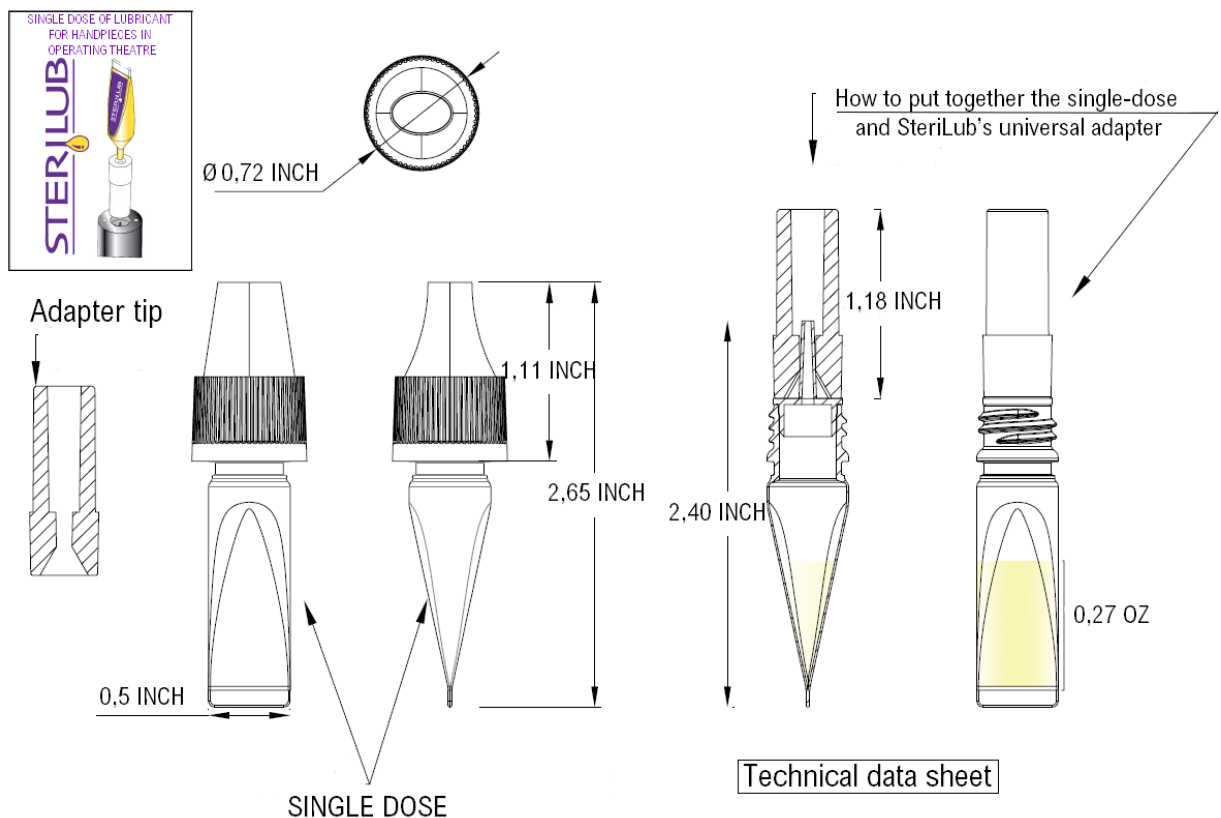
2. Device Information	
2.1	<u>Trade name</u> : STERILUB®
2.2	<u>Generic name</u> : Monodose de lubrifiant stérile
2.3	<u>Definition</u> : STERILUB® is a single dose of sterile single-use oil with its universal adapter for post-sterilisation lubrication of handpieces, contra angles and surgical motors.

2.4 Description of the device (including its photo, scheme, dimensions, volume, etc.) :

2.4.1 Product components

On the one hand, there is a single dose made of polyethylene (MARLEX HHM 5502BN) manufactured by blow moulding and containing 0.8 ml (0.028oz) of TURMOSYNTH VG 32 oil in accordance with the requirements of the European Pharmacopoeia. It is sealed with a safety screw cap which once unscrewed, shows a straight adapter tip.

On the other hand, there is a universal adapter tip made in polyethylene (PE 48 shore D) manufactured by injection moulding whose largest tip can be fixed onto the single-dose adapter tip.

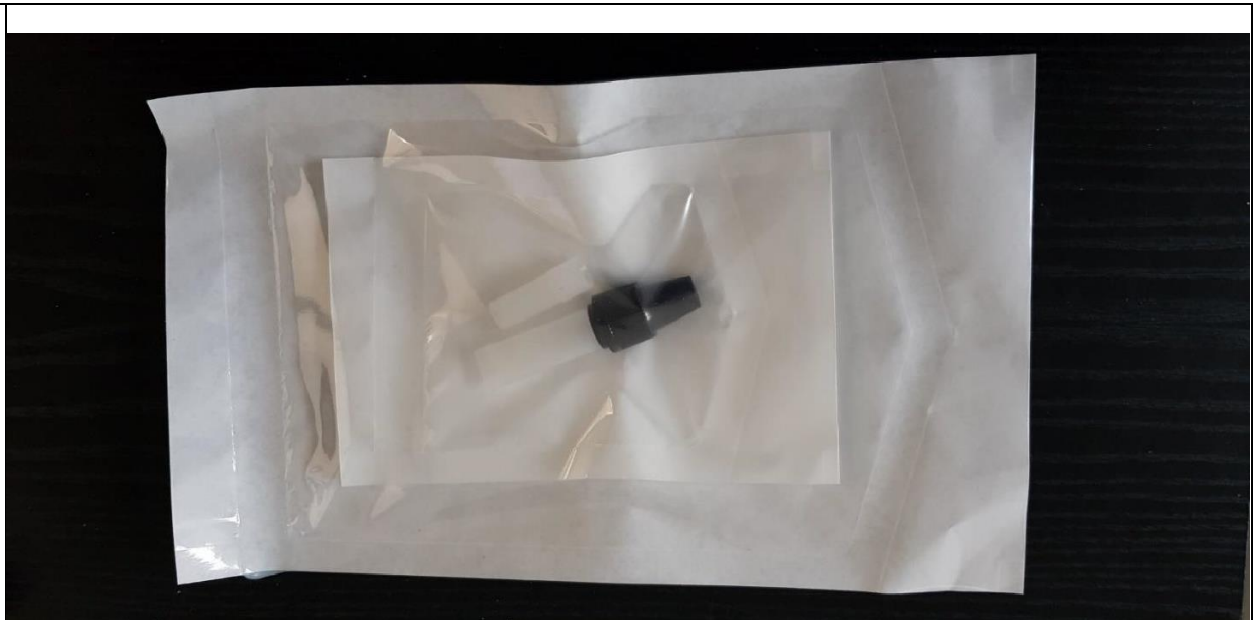


2.4.2 Packaging

In order to ensure the sterility of the product, the monodose and the universal adapter are grouped, without being assembled, in the first paper/plastic package with a how-to-use sticker on it. They are then packed in the second container that is the same quality as the first one but a larger size with a how-to-use scheme sticker on it. The dimensions are as follows:

- The first package is 150 x 100 mm (5.9 x 3.93 inches)
- The second package is 250 x 150 mm (9.84 x 5.9 inches)

The packages are made of paper type NR 60 GSM when it comes to the paper side and polyester type 48 PET/200 LDPE when it comes to the plastic part.



<p>2.6</p>	<p><u>DM classification</u> : I Sterile <u>Applicable EU Directive</u> : 93/42/CEE <u>According to Appendix No. VII</u> Notified body and number : Kiwa Cermet Italia (0476) Date of first placing on the market in the EU : waiting for CE label</p>
<p>2.7</p>	<p>Registration according to the nomenclature of the public procurement code :</p>
<p>2.8</p>	<p>Conditioning / Packaging : UCD : (Unité de commande) box of 100 single-doses CDT : (Multiple de l'UCD) QML : (Quantité minimale de livraison) 1 box of 100 single-doses with the dimensions 600 x 400 x 200 mm, for a total weight of 1.725 kg</p>
<p>2.9</p>	<p>Labelling: copy (facsimile) of the labelling template : see attached labelling UCD CDT QML Barcode</p>
<p>2.10</p>	<p>Devices and accessories associated with listing. Universal adapter tip delivered with the single-dose</p>
<p>2.11</p>	<p>Composition of the device : Main components:</p>

Component	Ingredient	CAS Number	Functions	Concentration by %	Per single dose ¹ (unitary formula)	Percentage (m/m)
Turmosynth VG 32 : White oil	Turmosynth VG 32 :	/	Lubricant	100 %	6.88g	100
	White mineral oil	8042-475	Base oil	99 %		
	Triphenyl phosphorothionate	597-82-0	Extreme / Pressure Antiwear additive	≤ 0,5 %		
	Hexamethylene bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	35074-77-2	Antioxidant	≤ 0,2 %		
	Benzenamine, N-phenyl-, reaction product with 2,4,4 trimethylpentene	68411-46-1	Antioxidant	≤ 0,1 %		
	Amines, C11-14-branched alkyl, monoheptyl and diheptyl phosphates	80939-62-4	Corrosion inhibitor / Antiwear additive	≤ 0,1 %		
	N,N-bis(2-ethylhexyl)-4-methyl-1H-benzotriazole-1-methylamine	80584-90-3	Metal deactivator	≤ 0,1 %		
	N,N-bis(2-ethylhexyl)-5-methyl-1H-benzotriazole-1-methylamine	80595-74-0	Metal deactivator	≤ 0,1 %		
Anti foaming agent	/	Defoaming agent	≤ 0,05 %			
Primary packaging	Packaging Elements	Raw Materials	CAS number	Characteristics	Functions	Reference to standard
	Single dose	ALCUDIA® 5502E high-density polyethylene copolymer of hexene	25213-02-9	Good environmental stress cracking resistance	Container of lubricating oil	Complies with : - US Food and Drug Administration (FDA) 21 Code of Federal Regulation (CFR) 177.1520 - Regulation (EC) 1935/2004 - Regulation (EC) 2082/2008
	Pipette	Formolene® HB5202B	25213-02-9	excellent stiffness and stress crack resistance properties	Immediate packaging	- U.S FDA 21 CFR 177.1520
	Safety cap	MAXITHEN HP 1279 Linear low-density polyethylene	13463-67-7	Excellent thermal stability	Safety cap	- Food compliant
Accessory	Universal tip	LDPE 780E Low Density Polyethylene Resin	9002-88-4	Excellent flow Good rigidity Good surface gloss	Inserting of the single dose in the handpiece	Complies with : - Canadian Health products and Food Branch (HPFB) No Objection - US FDA 21 CFR 177.1520

3. Sterilisation process :	
	Delivered in double sterile package
	Gamma ray sterilisation

4. Conditions of conservation and storage	
	Normal preservation & storage conditions : at room temperature, between 0 and 40°C, in a dry and dust-free place.
	Special precautions : do not exceed the expiry date
	Duration of the validity of the product : 5 years
	Presence of temperature indicators if applicable : NA

5. Safety in use	
5.1	Technical security : NA
5.2	Microbiological safety (if applicable) : NA (to complete) Registration number : NA

6. Advice for use	
6.1	Instructions for use : <ol style="list-style-type: none"> 1. Take the single dose out of the sterile package just before use. 2. Leave the adapter tip in the sterile package. 3. Hold the single dose cap up. Push down the security cap and unscrew. 4. Insert the widest side of the universal adapter onto the tip of the single dose. 5. Insert the narrow end of the universal tip into the bottom of the handpiece (T.I) as far as it will go (the handpieces which are used with E-TYPE micromotors) 6. Turn the handpiece assembly down, and STERILUB in upright position and squeeze the single dose twice to empty it completely 7. Remove the single dose and the universal adapter from the T.I 8. Switch on the handpiece 9. Hold the handpiece over a sterile gauze for 30 seconds in order to eliminate any excess oil. 10. Dispose of the single dose and universal adapter for recycling.
6.2	Indications : (CE norm) No contraindications to the use of Sterilub®, nor undesirable effects during the use on patients
6.3	Precautions of use : <ul style="list-style-type: none"> - Read the instructions carefully before using - Sterile medical device - Single use medical device - Dispose of the medical device after use - Do not resterilise - Do not use after the expiry date - Do not use if the packaging is damaged - Use all the oil contained in the single dose - Do not reuse STERILUB® due to the following risk:

	<ul style="list-style-type: none"> - Microbiological contamination of the handpiece - Insufficient lubrication for a second handpiece - Do not use single dose or adapter tip if they are dropped on the floor - Do not mix with another oil - Immediately clean any oil outside of the handpiece or contra angle - Do not use single dose without adapter tip - Do not use on a medical device unsuitable for the adapter tip - Store in a clean and dry place, protected from light. - Handle with gloves and mask - Store between 0°C (32°F) and 40°C (104°F)
7.	Additional information on the product
	<ul style="list-style-type: none"> - Contains the exact dose of oil (0,8ml) in each monodose according to the requirements of the manufacturers of handpieces and contra-angle handpieces for dentists and stomatologists. - Universal adapter tip for all handpieces and contra-angle handpieces that are used on a TYPE-E micromotor.
8.	List of appendices to the file
	<ul style="list-style-type: none"> CE certificate of conformity Labelling Instruction manual Brochure



Reg. Numero / Reg. Number	MED 31591	Revisione / Revision	0
Primo rilascio / First issue date	2021-02-24	Valido da / Valid from	2021-02-24
Scadenza / Valid until	2024-05-26	Ultima modifica / Last change date	2021-02-24

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CERTIFICATE

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:

CM Medical Sas

Sede Legale e Operativa / Legal and Operative Site:
14, Impasse de la Fosse
81100 Castres - France

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:

Sterile Oil to lubricate dental and stomatologist handpieces and contra angles

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cedriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.499.3.111
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E-mail: info@kiwacermet.it
www.kiwacermet.it

Rif. rapporto di audit/ Ref. audit report: del/dtd10.07/2020

Rif. analisi documentazione tecnica/ Ref. technical documentation analysis: del/dtd 01/02/2020

Chief Operating Officer
Giampiero Belcredi

Digitally signed by: BELCREDI GIAMPIERO
Date: 25/02/2021 09:06:10



Organismo Notificato n. 0476
Notified Body nr. 0476

CERMET



Reg. Numero /
Reg. Number MED 31591

Primo rilascio /
First issue date 2021-02-24

Scadenza /
Valid until 2024-05-26

Revisione /
Revision 0

Valido da /
Valid from 2021-02-24

Ultima modifica /
Last change date 2021-02-24

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CERTIFICATE

**Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate**

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Sterile Oil to lubricate dental and stomatologist handpieces and contra angles

Classe di rischio / Risk class:

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Radiation

Marca / Brandname:

Sterilub

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia. Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey. L'allegato tecnico è parte integrante del presente Certificato./ The technical sheet is an integrating part of this Certificate.

Kiwa Cermet Italia S.p.A.
Società con solo unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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40057 Granarolo dell'Emilia (BO)
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Fax +39 051 763 382
Email: info@kiwacermet.it
www.kiwacermet.it

CERMET

Chief Operating Officer
Giampiero Belcredi

Digitally signed by: BELCREDI GIAMPIERO
Date: 25/02/2021 09:06:59

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

EC Declaration of Conformity

According to Annex II of Directive 93/42/EEC on medical devices

We,
CM Medical
14 Impasse de la Fosse
81100 – CASTRES – France

Declare under our sole responsibility that the medical device

STERILUB

Classification : STERILUB® is a class Is medical device (in accordance with rule 1 of the annex IX of European Council Directive 93/42/EEC)

Complies with all the applicable requirements of Directive 93/42/EEC

Name and identification of the notified body : Kiwa Cermet Italia (Notified Body number : 0476) with the address of the headquarters : Via Cadriano, 23, 40057 Granarolo dell'Emilia BO,

This, for the period of validity of the certificate, i.e. until: 26/05/2024

Done at Castres on 26/02/2020

Christophe MICHEAU, CEO

