astec

ASTEC CO., LTD – Fukuoka, Japan

EC Declaration of Conformity

We,

ASTEC CO., LTD.
4-6-15, Minamozato, Shime
Kasuya, Fukuoka, Japan, 811-2207

Declare under sole responsibility, that one of our products

APC-30DR Water Jacketed CO2 Incubator

Fulfills the safety requirements of the following technical standard

EN 61010-1:2010, AMD1:2016

[Emission] EN 61326-1:2013, IEC 61326-1:2012 (Class A)
[Immunity] EN 61326-1:2013, IEC 61326-1:2012 (Controlled Electromagnetic Environment)
FCC 47 CFR Part 15, Part 15,
ANSI C63.4-2014

March 24, 2022
Date of Issue

Takeo Cho
Chief Marketing Officer
General Manage, Global Sales

ASTEC CO., LTD.
4-6-15, Minamizato, Shime, Kasuya
Fukuoka, Japan, 811-2207
Tel: +81-92-935-5585
Fax: +81-92-936-6613
Mail: info@astec-bio.com

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ASTEC CO., LTD – Fukuoka, Japan

EC Declaration of Conformity

We,

ASTEC CO., LTD.
4-6-15, Minamozato, Shime
Kasuya, Fukuoka, Japan, 811-2207

Declare under sole responsibility, that one of our products

Innovative Blastocyst Incubation System
1) CCM-iBIS-SL-120LE, CCM-iBIS-SG-230LE
2) CCM-iBIS-SL-230LE, CCM-iBIS-SG-230LE

Fulfills the safety requirements of the following technical standard

IEC 61010-1:2010+A1

This declaration is based upon the test report, Report No. 50290024 001 and CB Certificate No. JPTUV-104962 issued by TUV Rheinland Japan Ltd.

Takeo Cho
Chief Marketing Officer
General Manager, Global Sales / ASTEC CO., LTD

February 25th, 2022

ASTEC CO., LTD.
4-6-15, Minamizato, Shime, Kasuya
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Tel: +81-92-935-5585
Fax: +81-92-936-6613
Mail: info@astec-bio.com

KITAZATO®

EC DECLARATION OF CONFORMITY

Manufacturer:		**Kitazato Corporation** **Address: 100-10 Yanagishima, Fuji, Shizuoka 416-0932 Japan** **Phone: +81-545-65-7122 Fax: +81-545-65-7128** **E-mail: info@kitazato.co.jp**
European Representative:		**Dibimed - Biomedical Supply, S.L.** **Address: C/ Jorge Comín, 3 Bajo 1-2, 46015 Valencia, Spain** **Phone: +34-963-056-395 Fax: +34-963-056-396** **E-mail : info@dibimed.com**
Product:	**Trade Name:**	**Cryotop**
	Code number:	**Cryotop® (G) Ref: 81111 / Cryotop® (R) Ref: 81112** **Cryotop® (W) Ref: 81113 / Cryotop® (B) Ref: 81114** **Cryotop® (Y) Ref: 81115** **Cryotop®SC (G) Ref: 81121 / Cryotop®SC (R) Ref: 81122** **Cryotop®SC (W) Ref: 81123 / Cryotop®SC (B) Ref: 81124** **Cryotop®SC (Y) Ref: 81125**
	Description:	**A PET-film attached to ABS-handle and equipped with a straw cap, used to load and store oocytes or embryos in vitrification and for preservation.**
	Classification:	**Class II a** **Rule 2 according to Annex IX of the MDD**
Conformity Assessment Route:		**Annex V applied**

We hereby declare that the above-mentioned devices comply with the (legislation of the member states where the Notified Body is located - if a Notified Body is involved -) transposing European Medical Devices Directive 93/42/EEC.
Kitazato Corporation is solely responsible for this Declaration of Conformity.

General applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), as amended by Directive 2007/47/EC.

Standards: Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are as per the "LIST OF APPLIED STANDARDS".

Notified Body: BSI Group The Netherlands B.V. (ID #: 2797)
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Tel: +31-20-346-0780

EC Certificate: Standard: EN ISO 13485:2016
EC Certificate #: 548538
Issued by: BSI

Signature: _____ Date: May 20, 2021

Name: Futoshi INOUE
Position: President and Representative Director, Kitazato Corporation

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By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 69386**

Issued To: **CooperSurgical Inc.,**
also trading as Ackrad Laboratories,
Prism Healthcare, Milex, Medscand,
Wallach Surgical Devices,
SAGE In-Vitro Fertilization and
Lone Star Medical Products
95 Corporate Drive, Trumbull,
Connecticut
06611
USA

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2002-08-30** Date: **2020-03-13** Expiry Date: **2024-05-26**

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Certificate No: CE 69386

Certificate Scope:

The manufacture of Ophthalmic, Gynaecology and dermatology Cryosurgery Systems and accessories.

The manufacture of sterile and non-sterile obstetrics and gynaecology devices including;

- **Uterine Manipulators/Injectors and their accessories including colpotomizer cups**
- **Vaginal Pessaries**
- **Amniocentesis Needles**
- **Vacuum assisted Delivery systems and accessories**
- **Infant warmers**
- **Fetal and Vascular Ultrasound Dopplers**

The manufacture of sterile and non-sterile Artificial Reproductive Technology (ART) devices including;

- **Oocyte recovery needles**
- **Incubators**
- **Micropipettes**
- **Stripper Tips**

The manufacture of sterile general surgery devices including;

- **Esophageal ballon Catheters**
- **Laparoscopic cannulas/trocars**
- **Laparoscopic Port Closure Systems**
- **Stays, retractors and retractor kits**

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of;

Intrauterine Insemination Catheters, Embryo Replacement Catheters, Pasteur pipettes, Assisted Hatching pipettes, Laparoscopic Smoke Evacuation Systems, Hysteroscopy Saline/Air Contrast Injectors, Diagnostic Surveillance Cannulas, Adapter Drapes, Hysterosalpingography Catheters, Bi-nasal Oxygen Cannulas, Cervical Dilators, Gynaecological tissue sampling devices.

Those aspects of Annex V relating to metrology in the manufacture of;
Vaginal Pessary Fitting Kit and Contraceptive Diaphragm fitting sets

First Issued: **2002-08-30** Date: **2020-03-13** Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 69386

Issued To:

CooperSurgical Inc.,
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95 Corporate Drive, Trumbull,
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06611
USA

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1103	Medical Heat Packs	---
MD 1302	Ultrasound dopplers	---
MD 1104	Cryosurgical systems	---
MD 1402	IVF Incubators G185 & G210	---
MD 0106	Adult Esophageal Balloon Catheter Set	---
MD 0106	Milex® Pessaries (Short term)	---
MD 0106	Uterine Manipulators/Injectors and Accessories	---
MD 0106	Fetal vacuum extraction system and Accessories	---
MD 0106	Carter-Thomason CloseSure System®	---
MD 0106	Stays and Retractors	---
MD 0106	Apple-Hunt Secondary Trocar Cannula	---
MD 0106	Carter-Thomason® II Port Closure System Suture Passer	---
MD 0102	Wallace® Amniocentesis Needle	---
MD 0109	Wallace® Oocyte Recovery Set	---
MD 0109	Micropipettes	---
MD 0109	Stripper Tips	---

First Issued: **2002-08-30** Date: **2020-03-13** Expiry Date: **2024-05-26**

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Supplementary Information to CE 69386

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06611
USA

Number	Device Name	Intended purpose per IFU
Class Is		
MD 0106	Lone Star Retractor Rings	---
MD 0109	Pasteur Pipettes	---
MD 0109	Origio Assisted Hatching Pipettes	---
MD 0101	INCA® Nasal Cannula Set with sterile nasal prongs	---
MD 0109	Intrauterine Insemination Catheters	---
MD 0106	Cytology Sampling devices	---
MD 0106	Endometrial Suction Curette	---
MD 0106	Hysterosalpingography Catheter	---
MD 0106	Laparoscopic Smoke Evacuation Systems	---
MD 0106	Wallach Disposable OS Finders	---
MD 0106	CSI OS Finders	---
MD 0106	ABBI (Air Bubble Base Infuser)	---
MD 0106	EndoSee® Cannula	---
MD 0106	Sterile Adapter Drapes	---
MD 0109	Embryo Replacement Catheters	---
Class Im		
MD 0107	Vaginal Diaphragms Fitting Sets	---
MD 0106	Milex Pessaries Fitting Kit	---

First Issued: **2002-08-30** Date: **2020-03-13** Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 69386**
Date:	**2020-03-13**
Issued To:	**CooperSurgical Inc., also trading as Ackrad Laboratories, Prism Healthcare, Milex, Medscand, Wallach Surgical Devices, SAGE In-Vitro Fertilization and Lone Star Medical Products 95 Corporate Drive, Trumbull, Connecticut 06611 USA**

Subcontractor:	**Service(s) supplied**
Cooper Medical SRL Edificio N° B49, 51 Ave 0 Parque Industrial Zona Franca Coyol La Garita, Alajuela Costa Rica	**Manufacture**
CooperSurgical Distribution B.V Celsiusweg 35 5928 PR Venlo The Netherlands	**EU Representative**
Drummond Scientific 500 Parkway Broomall PA 19008 USA	**Crucial Supplier**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

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Subcontractor:	**Service(s) supplied**
Isomedix Operation, Inc. North Facility 1880 Industrial Drive Illinois 60048 USA	**Gamma Irradiation** **Gamma Sterilization**
Isomedix Operations, Inc 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	**ETO Sterilization**
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	**Gamma Irradiation** **Gamma Sterilization**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

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Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	**Gamma Irradiation** **Gamma Sterilization**
Lone Star Medical Products 11211 Cash Road Stafford Texas 77477 USA	**Manufacture**
Origio a/s Knardrupvej 2 2760 Måløv Denmark	**EU Representative**

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Directive 93/42/EEC on Medical Devices, Annex V

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Subcontractor:	**Service(s) supplied**
Pristech Products Inc. 6952 Fairgrounds Parkway San Antonio Texas 78238 USA	**Manufacture**
Research Instruments Ltd. Bickland Industrial Park Falmouth TR11 4TA United Kingdom	**Manufacture**
Sterigenics US,LLC 84 Park Road Queensbury NY 12804 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Sterilization Services of Tennessee, Inc. 2396 Florida Street Memphis Tennessee 38109 USA	**ETO Sterilization**
UNISIS CORP. Saitama Plant 2675-1 Nishikata Koshigaya-shi Saitama 343-0822 Japan	**Crucial Supplier**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 69386**

Date: **2020-03-13**

Issued To: **CooperSurgical Inc.,
also trading as Ackrad Laboratories,
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Wallach Surgical Devices,
SAGE In-Vitro Fertilization and
Lone Star Medical Products
95 Corporate Drive, Trumbull,
Connecticut
06611
USA**

Date	Reference Number	Action
30 August 2002	4316414	Original issue to CooperSurgical Inc for the manufacture of Fetal Dopplers and Sterile Disposable Uterine Manipulator-Injectors.
04 October 2002	4386116	Amended certificate to add Sterile Colpotomizer Systems to scope.
12 November 2002	4386116	Amended certificate to add the trading name of Ackrad Laboratories Inc. Also amended scope to include INCA Nasal Cannulae Set with sterile nasal prongs and Sterile Bronchitrac Suction Catheters, Esophageal Balloon Catheters, Elliptosphere Catheters, Tampa Catheters and H/S Catheter sets with Kraton Balloons.
28 January 2004	4487082	Amended certificate to add the trading name of Prism Healthcare. Also amended scope to include Gelpacks for heat therapy, sterile and non-sterile Vacuum Assisted Delivery Pumps, sterile Vacuum Assisted Delivery Extractor Cups and Delivery Kits. Also added a new subcontractor Pristech Products Inc as manufacture of gelpacks for heat therapy.
25 February 2004	n/a	Correction of typographical error to address.

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 69386**

Date: **2020-03-13**

Issued To: **CooperSurgical Inc.,**
also trading as Ackrad Laboratories,
Prism Healthcare, Milex, Medscand,
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Lone Star Medical Products
95 Corporate Drive, Trumbull,
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USA

Date	Reference Number	Action
22 July 2004	4593904	Amended certificate to add the trading name of SAGE In-Vitro Fertilization Inc. Also, amended scope to include sterile oil and sterile water for Tissue Culture for use in in-vitro fertilization, and Sterile Phosphate Buffered Saline (PBS) for use in in-vitro fertilization Also, modified the Supplementary Information to highlight Class I Sterile devices.
27 September 2004	4634606	Amended certificate to include Vascular Dopplers within the scope.
30 November 2004	4647383	Amended certificate to include Ophthalmic Cryosurgery Systems within the scope.
27 April 2005	4657997	Amended certificate to include trading name of Milex and amended scope to include Sterile Curettes and Contraceptive Diaphragm fitting sets.
19 September 2005	4739488	Extension of scope to include Fiberoptic Cystometry System, Sterile Fiberoptic Catheter and Cytology Sampling devices.
16 July 2007	7073121	Certificate renewal. Extension to scope to include Embryo Transfer Catheters.
30 October 2007	7110759	Extension to scope to include Intrauterine Insemination Catheters.

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 69386**

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Date	Reference Number	Action
23 May 2008	7213846	Extension to scope to include Cryosurgery Systems for gynaecology and dermatology. Also addition of Wallach Surgical Devices as a trading name.
23 June 2008	7226858	Extension to scope to include CT CloseSure Systems and CT CloseSure Systems XL.
22 October 2008	7284056	Extension to scope to include endometrial suction curettes.
31 March 2010	7507745	Addition of Lone Star Medical Products as a trading name and addition of Sterile Surgery Kits, Retractor Kits, Stays, Dilamezinsert and Sterile Retractors to scope. These were covered by Lone Star Medical Products BSI CE 553016 issued on 12 October 2009 which was originally transferred from SGS where Lone Star Medical Products, Inc. was certified since 4 February 1998. Steris Isomedix Services, Inc., Coventry, RI - Sterilization was removed and three new Subcontractors were added: Steris Isomedix, So. Plainfield, NJ - ETO Sterilization; Leisegang Feinmechanik GmbH, Berlin, Germany - EU Representative; and Lone Star Medical Products, Stafford, TX – Manufacture. With this revised certificate, CE 69386, the previous certificate CE 553016 is cancelled.

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
02 August 2010	7548521	Addition of Sterigenics US, LLC, 84 Park Road, Glen Falls, New York, 12804, to the list of significant subcontractors for ETO sterilization.
24 February 2011	7650994	Addition of Laparoscopic Smoke Evacuation Systems to scope. Addition of significant subcontractor Biotest Laboratories, Inc.
13 February 2012	7752683	- Revised format of supplementary pages for clarity. - Addition of vaginal pessaries to scope. - Revision of the following devices to "Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of". INCA Nasal Cannulae Set with sterile nasal prongs. Intrauterine Insemination Catheters. - Revision of the following devices to "Manufacture of". Vacuum Assisted Delivery Pumps. Sterile Elliptosphere Catheters. Sterile Tampa Catheters. Sterile *H/S* Catheters sets with Kraton Balloons.

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
13 February 2012 (continued)	7752683	- Removal from certificate scope of. Oil for Tissue Culture for use in in-vitro fertilization. Phosphate Buffered Saline (PBS) for use in in-vitro fertilization. Water for Tissue Culture for use in in-vitro fertilization. - Addition of Steris Isomedix, Libertyville as a significant subcontractor. Removal of Steris Isomedix, Waukegan and Isomedix Operation Inc as significant subcontractors. Removal of sterilisation and testing activities for significant subcontractor Biotest Laboratories. Clarification of sterilisation method (Gamma Irradiation) for significant subcontractor Steris Isomedix, Northborough.
12 June 2012	7828419	Extension to scope of manufacturing to include Trocars, Cannulas and Trocar/Cannula Kits and Retractors. Addition of 'Emergo Europe, Netherlands' as EU Representative.

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Date	Reference Number	Action
09 August 2012	7868380	Certificate Renewal. Removal of 'Biotest Laboratories, Inc' as significant subcontractor.
23 July 2013	8022947	Addition of Vaginal Pessary Fitting Kit.
29 November 2013	8075064	Revision of the following devices to "Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of". Elliptosphere catheters, *H/S* catheter sets with kraton balloons and tampa catheters. Removal of Sterile Bronchitrac suction catheters from scope.
10 June 2015	7982958	Addition of Limb Plethysmography Systems.
08 September 2015	8413506	Addition of Sterile ABBI.
06 November 2015	8429989	Addition of Endosee Cannulas.
11 March 2016	8485008	Removal of SAGE In-Vitro Fertilization as significant subcontractor.
23 June 2016	8548511	Addition of Sterile Os Finder Cervical Dilator, Sterile Disposable Smoke Evacuation Tubing with Attached Speculum Tubing, and Sterile Adapter Drape.

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Date	Reference Number	Action
07 August 2017	8695527	Certificate Renewal. Change of address for Emergo Europe. Change of address for Sterigencics US, LLC. Change of name for Steris Isomedix Services to Isomedix Operations, Inc. Removal of Sterile Disposable Smoke Evacuation Tubing with Attached Speculum Tubing.
26 January 2018	8887080	Addition of IVF Incubators. Addition of Research Instruments as a significant subcontractor.
23 October 2018	8922778	Addition of Amniocentesis Needles, Embryo Replacement Catheters, and Oocyte Recovery Needles. Addition of Cooper Medical SRL, Sterilization Services of Tennessee Inc., and UNISIS CORP as significant subcontractors.
19 February 2019	9719699	Traceable to NB 0086.
24 January 2020	3143385	Removal of Leisegang Feinmechanik GmbH EU Representative. Addition of CooperSurgical Distribution B.V. as EU Representative.

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06611
USA**

Date	Reference Number	Action
Current	9770590	Certificate renewal. Origio a/s added as EU Representative. Drummond Scientific added as Crucial Supplier Isomedix Operations, Inc. (9 Apollo Drive) added as significant subcontractor for Gamma Irradiation/Gamma Sterilization. Removal of Sterile Surgery Kits, Dilamezinsert, Limb Plethysmography Systems, Fiberoptic Cystometry Systems and Fiberoptic Catheters from scope. Embryo Transfer Catheters removed from scope as it is covered by Embryo replacement catheters. Added Micropipettes, Stripper Tips and Pasteur/Assisted Hatching pipettes to scope. The scope has been reformatted to better reflect the certified devices and make the expression more understandable.

CERTIFICATE OF CONFORMANCE

CoC REFERENCE: ADS.STP.COC_001

MANUFACTURER: ARQUIMEA ADS

PRODUCT DESCRIPTION:	**PART NUMBER:**
Spermtrack	STP'10'DB.0321060020; STP'10'SB.0321060020; STP'10'R.0321060020; STP'10'G.0321060020
DATE CODE/LOT REFERENCE:	**Qty:** 15 (db), 15 (SB), 15 (R), 5 (G)
1222	**S/Ns:** 009-023 (DB); 009-023 (SB), 008-022 (R), 004-008 (G)

CONTRACT NUMBER:
OV/22/06/00018

APPLICABLE SPECIFICATIONS:
NA

With this document ARQUIMEA ADS S.L.U. certifies that the product described here above meets all the quality and performance requirements defined in the applicable specifications and in accordance with the Project or Contract requirements.

OTHER DOCUMENTS

	Reference:	**Attached: Y/N**
☐ **TEST**	N/A	N
☒ **TRACEABLITY**	(This document)	N
☐ **OTHER**	N/A	N

RFW/RFD/NCR:

PROJECT REFERENCE: 0620[01]0206
PROJECT NAME: Spermtrack

REMARK:
NA

Signed:	Signed:
ARQUIMEA ADS Project Manager	ARQUIMEA ADS PA Manager
Date: 22/03/2022	Date: 22/03/2022