

TECHNICAL DATA SHEET STERIDIAMOND - STERIPERFECT POUCHES AND ROLLS	Mod. TDS19 EN
	Rev. 12
	December 2017

MANUFACTURER IDENTIFICATION

E.C.S. S.r.l.
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PRODUCT IDENTIFICATION

Class / Definition

Non-invasive devices, belonging to Class I, applicable rule n°1 of the Annex IX to the European Directive 93/42/CEE and following integrative modifies, such those provided by DL 25/01/2010 n. 37, acknowledging the European Directive 2007/47/CE. « none of the rules following the rule no.1 are applicable ».

Note: in the technical dossier, the indication “MDD 93/42” means the following complete sentence “D.L. 46/97, acknowledging the European Directive 93/42/CEE, and further integrations and modifies, such as those provided by D.L. n. 37 of 25/01/2010, acknowledging the European Directive 2007/47/CE”

PRODUCT DESCRIPTION

E.C.S. S.r.l. is the manufacturer of the following medical devices: STERIDIAMOND – STERIPERFECT, pouches and rolls.

STERIDIAMOND - STERIPERFECT pouches and rolls have been designed to be used in hospitals and dental centers by anyone who needs to have the instruments or other medical devices sterilized by STEAM, EO and FORM.

STERIDIAMOND - STERIPERFECT pouches and rolls are disposable devices and they shall not be reused. The product is made of medical paper (60g/sq.m) and plastic film made of polyester and polypropylene (PET/PP).

The employed paper is white colour and resistant to humidity. It has been developed in order to ensure a high level of protection against bacteria.

All prints, including chemical indicators for STEAM, EO and FORM, are positioned on the paper side in order to prevent the contamination of the medical devices with the ink and avoiding any release of potential polluting substances on the product itself (in compliance with EN ISO 11607-1-2 and UNI EN 868-5:2009 standards) with indications for the interpretation of the results in Italian, English, Spanish and Portuguese.

The product is designed to be welded.

Continuous hot and multi-line welding with rounded corners are always made in order to prevent any deposit of dirt, thus reducing the risk of contamination of the content during stocking and upon package opening.

In compliance to European Directive 2007/47/CE, modifying the European Directive 93/42/CEE, ECS Srl declares that :

1. "STERIDIAMOND - STERIPERFECT " medical devices do not contain, as integrant part, any substance deriving from human blood as per point 7.4 of Annex I of abovementioned Directive:
2. no compound of animal origin has been used during production as per the Directive 2003/32/CE.

Airuno, December 2017

In witness
E.C.S. S.r.l.
General Manager
IVANO REDAELLI

TECHNICAL CHARACTERISTICS

- Plastic film made of coloured polyester/polypropylene and white medical paper. The plastic film is transparent in order to allow a clear identification of the contents. The medical paper is highly resistant to tearing and humidity.
- Suitable for STEAM, EO and FORM sterilization. The indicators are placed on the product in compliance with the norm UNI EN 868-5.
- STEAM process indicator turns from pink to brown.
- EO process indicator turns from blue to brown.
- FORM process indicator turns from burgundy to green.
- The indicator changes color process is described in different languages.
- Lot number for a complete traceability.
- Pouches can be easily opened by using special invitation.
- Minimal release of fiber during opening thanks to the features of the medical paper.

E.C.S. S.r.l. performed at qualified laboratory a "Packaging Validation" (Report No. 02/2015 for pouches and Report No. 03/2015 for rolls) according to which we confirm that the packaging (considering the three pre-welded sides by the manufacturer) do not result to be damaged after the process of accelerated ageing compared with samples not subjected to ageing.

After the ageing process, simulant 5 years natural shelf-life, validation tests of the packaging were conform to requirements of the reference standards UNI EN ISO 868-5, EN ISO 11607-1 and 11607-2.

In addition, E.C.S. S.r.l. performed at qualified laboratory a "printed indicators validation" (Report No. 13/2015) according to UNI EN ISO 11140-1:2014 which shows conformity of the indicators operation.

PACKAGING

Pouches and rolls are wrapped in a transparent film in order to ensure their protection against dust, even after opening the cardboard box and to facilitate the transportation of the products in those areas where the cardboard box can not be brought in.

STORAGE CONDITIONS

Avoid direct exposure to sunlight or heat sources and store in environments avoiding any contamination.

Keep away from heat, light and humidity sources.

Rotate your stock accordingly to arrival order and handle with care.

HEALTH AND SAFETY

When STERIDIAMOND - STERIPERFECT pouches and rolls are correctly used, there are no special precautions to adopt during their handling and use.

These products do not contain toxic agents or material.

Considering the material employed, we declare that the products are free from phthalates, cancerogenic, mutagenic or toxic substances to reproduction.

Airuno, December 2017

CND CLASSIFICATION – DIRECTORY NAME

Commercial name	CND classification	Directory number	Producer
Flat pouches and self-sealing pouches Steridiamond/Steriperfect	S01010101 – flat pouches in coupled plastic paper/film for sterilization.	96701/R	E.C.S. SRL
Gussetted pouches Steridiamond	S01010102 – Gussetted pouches in coupled paper/film for sterilization	1452804/R	E.C.S. SRL
Flat rolls Steridiamond/Steriperfect	S01020101 – flat rolls in coupled plastic paper/film for sterilization	96767/R	E.C.S. SRL
Gussetted rolls Steridiamond	S01020102 – Gussetted rolls in coupled plastic paper/film for sterilization	98820/R	E.C.S. SRL

CODES, DIMENSIONS AND PACKAGING

a) STERIDIAMOND LINE

SRP - STERIDIAMOND FLAT ROLLS 100MT

REF	DIMENSIONS	PACKAGING
SRP0510	55 MM. X 100 MT.	8 pieces
SRP7510	75 MM. X 100 MT.	8 pieces
SRP1010	100 MM. X 100 MT.	4 pieces
SRP12510	125 MM. X 100 MT.	4 pieces
SRP1510	150 MM. X 100 MT.	4 pieces
SRP2010	200 MM. X 100 MT.	2 pieces
SRP2510	250 MM. X 100 MT.	2 pieces
SRP3010	300 MM. X 100 MT.	2 pieces
SRP3510	350 MM. X 100 MT.	1 piece
SRP4010	400 MM. X 100 MT.	1 piece
SRP5010	500 MM. X 100 MT.	1 piece

*Other measures available on request

SRP - STERIDIAMOND FLAT ROLLS 200MT

REF	DIMENSIONS	PACKAGING
SRP0520	55 MM. X 200 MT.	8 pieces
SRP7520	75 MM. X 200 MT.	8 pieces
SRP1020	100 MM. X 200 MT.	4 pieces
SRP12520	125 MM. X 200 MT.	4 pieces
SRP1520	150 MM. X 200 MT.	4 pieces
SRP2020	200 MM. X 200 MT.	2 pieces
SRP2520	250 MM. X 200 MT.	2 pieces
SRP3020	300 MM. X 200 MT.	2 pieces
SRP3520	350 MM. X 200 MT.	1 piece
SRP4020	400 MM. X 200 MT.	1 piece
SRP5020	500 MM. X 200 MT.	1 piece

* Other measures available on request

SRS - STERIDIAMOND GUSSETED ROLLS

REF	DIMENSIONS	PACKAGING
SRS7510	75 MM. X 25 MM. X 100 MT.	8 pieces
SRS1010	100 MM. X 50 MM. X 100 MT.	4 pieces
SRS1510	150 MM. X 65 MM. X 100 MT.	4 pieces
SRS2010	200 MM. X 55 MM. X 100 MT.	2 pieces
SRS2510	250 MM. X 65 MM. X 100 MT.	2 pieces
SRS3010	300 MM. X 80 MM. X 100 MT.	2 pieces
SRS3510	350 MM. X 80 MM. X 100 MT.	1 piece
SRS4010	400 MM. X 80 MM. X 100 MT.	1 piece

* Other measures available on request

SBA - STERIDIAMOND SELF-SEALING POUCHES

REF	DIMENSIONS	PACKAGING	
		CARDBOARD	BOX
SBA60100	60 MM. X 100 MM.	3.600 pieces	200 pieces
SBA7525	75 MM. X 250 MM.	1.800 pieces	200 pieces
SBA90165	90 MM. X 165 MM.	1.800 pieces	200 pieces
SBA0925	90 MM. X 250 MM.	1.800 pieces	200 pieces
SBA1335	130 MM. X 350 MM.	1.200 pieces	200 pieces
SBA1426	140 MM. X 260 MM.	1.200 pieces	200 pieces
SBA1933	190 MM. X 330 MM.	1.200 pieces	200 pieces
SBA1940	190 MM. X 400 MM.	1.200 pieces	200 pieces
SBA3037	300 MM. X 370 MM.	800 pieces	200 pieces
SBA3045	300 MM. X 450 MM.	800 pieces	200 pieces
SBA3050	300 MM. X 500 MM.	800 pieces	200 pieces

* Other measures available on request

SBP - STERIDIAMOND FLAT POUCHES

REF	DIMENSIONS	PACKAGING
SBP7520	75 MM. X 200 MM.	2.000 pieces
SBP7525	75 MM. X 250 MM.	2.000 pieces
SBP7530	75 MM. X 300 MM.	2.000 pieces
SBP7545	75 MM. X 450 MM.	2.000 pieces
SBP1015	100 MM. X 150 MM.	2.000 pieces
SBP1020	100 MM. X 200 MM.	2.000 pieces
SBP1025	100 MM. X 250 MM.	2.000 pieces
SBP1030	100 MM. X 300 MM.	2.000 pieces
SBP1035	100 MM. X 350 MM.	2.000 pieces
SBP1040	100 MM. X 400 MM.	2.000 pieces
SBP1055	100 MM. X 550 MM.	2.000 pieces
SBP1220	120 MM. X 200 MM.	1.000 pieces
SBP1520	150 MM. X 200 MM.	1.000 pieces
SBP1525	150 MM. X 250 MM.	1.000 pieces
SBP1530	150 MM. X 300 MM.	1.000 pieces
SBP1535	150 MM. X 350 MM.	1.000 pieces
SBP1540	150 MM. X 400 MM.	1.000 pieces
SBP1622	160 MM. X 225 MM.	1.000 pieces
SBP1635	160 MM. X 350 MM.	1.000 pieces
SBP2025	200 MM. X 250 MM.	1.000 pieces
SBP2030	200 MM. X 300 MM.	1.000 pieces
SBP2035	200 MM. X 350 MM.	1.000 pieces
SBP2040	200 MM. X 400 MM.	1.000 pieces
SBP2050	200 MM. X 500 MM.	1.000 pieces

REF	DIMENSIONS	PACKAGING
SBP2128	210 MM. X 280 MM.	1.000 pieces
SBP2530	250 MM. X 300 MM.	1.000 pieces
SBP2535	250 MM. X 350 MM.	1.000 pieces
SBP2540	250 MM. X 400 MM.	1.000 pieces
SBP2545	250 MM. X 450 MM.	1.000 pieces
SBP2550	250 MM. X 500 MM.	1.000 pieces
SBP2745	270 MM. X 450 MM.	1.000 pieces
SBP3040	300 MM. X 400 MM.	1.000 pieces
SBP3050	300 MM. X 500 MM.	1.000 pieces
SBP3055	300 MM. X 550 MM.	1.000 pieces
SBP3057	300 MM. X 570 MM.	1.000 pieces
SBP3250	320 MM. X 500 MM.	500 pieces
SBP3260	320 MM. X 600 MM.	500 pieces
SBP3550	350 MM. X 500 MM.	500 pieces
SBP3658	360 MM. X 580 MM.	500 pieces
SBP4050	400 MM. X 500 MM.	500 pieces
SBP4055	400 MM. X 550 MM.	500 pieces
SBP4060	400 MM. X 600 MM.	500 pieces
SBP4250	420 MM. X 500 MM.	500 pieces
SBP4260	420 MM. X 600 MM.	500 pieces
SBP5060	500 MM. X 600 MM.	500 pieces
SBP6060	600 MM. X 600 MM.	500 pieces

* Other measures available on request

Pouches are strapped in bats of 200/250 pieces.

SBS - STERIDIAMOND GUSSETTED POUCHES

REF	DIMENSIONS	PACKAGING
SBS1540	150 MM. X 50 MM. X 400 MM.	500 pieces
SBS2040	200 MM. X 55 MM. X 400 MM.	500 pieces
SBS2050	200 MM. X 55 MM. X 500 MM.	500 pieces
SBS2550	250 MM. X 65 MM. X 500 MM.	500 pieces
SBS3050	300 MM. X 80 MM. X 500 MM.	500 pieces
SBS3058	300 MM. X 80 MM. X 580 MM.	500 pieces
SBS4258	420 MM. X 90 MM. X 580 MM.	500 pieces

* Other measures available on request

b) STERIPERFECT LINE

RP - STERIPERFECT FLAT ROLLS 100MT

REF	DIMENSIONS	PACKAGING
RP0510	55 MM. X 100 MT.	8 pieces
RP7510	75 MM. X 100 MT.	8 pieces
RP1010	100 MM. X 100 MT.	4 pieces
RP12510	125 MM. X 100 MT.	4 pieces
RP1510	150 MM. X 100 MT.	4 pieces
RP2010	200 MM. X 100 MT.	2 pieces
RP2510	250 MM. X 100 MT.	2 pieces
RP3010	300 MM. X 100 MT.	2 pieces
RP3510	350 MM. X 100 MT.	1 piece
RP4010	400 MM. X 100 MT.	1 piece
RP5010	500 MM. X 100 MT.	1 piece

*Other measures available on request

RP - STERIPERFECT FLAT ROLLS 200MT

REF	DIMENSIONS	PACKAGING
RP0520	55 MM. X 200 MT.	8 pieces
RP7520	75 MM. X 200 MT.	8 pieces
RP1020	100 MM. X 200 MT.	4 pieces
RP12520	125 MM. X 200 MT.	4 pieces
RP1520	150 MM. X 200 MT.	4 pieces
RP2020	200 MM. X 200 MT.	2 pieces
RP2520	250 MM. X 200 MT.	2 pieces
RP3020	300 MM. X 200 MT.	2 pieces
RP3520	350 MM. X 200 MT.	1 piece
RP4020	400 MM. X 200 MT.	1 piece
RP5020	500 MM. X 200 MT.	1 piece

*Other measures available on request

SRSB – STERIDIAMOND GUSSETED ROLLS BLUE FILM

REF	DIMENSIONS	PACKAGING
SRS7510B	75 MM. X 25 MM. X 100 MT.	8 pieces
SRS1010B	100 MM. X 50 MM. X 100 MT.	4 pieces
SRS1510B	150 MM. X 65 MM. X 100 MT.	4 pieces
SRS2010B	200 MM. X 55 MM. X 100 MT.	2 pieces
SRS2510B	250 MM. X 65 MM. X 100 MT.	2 pieces
SRS3010B	300 MM. X 80 MM. X 100 MT.	2 pieces
SRS3510B	350 MM. X 80 MM. X 100 MT.	1 pieces
SRS4010B	400 MM. X 80 MM. X 100 MT.	1 pieces

*Other measures available on request

BA - STERIPERFECT SELF-SEALING POUCHES

REF	DIMENSIONS	PACKAGING	
		CARDBOARD	BOX
BA60100	60 MM. X 100 MM.	3.600 pieces	200 pieces
BA75250	75 MM. X 250 MM.	1.800 pieces	200 pieces
BA90165	90 MM. X 165 MM.	1.800 pieces	200 pieces
BA90250	90 MM. X 250 MM.	1.800 pieces	200 pieces
BA13350	130 MM. X 350 MM.	1.200 pieces	200 pieces
BA14260	140 MM. X 260 MM.	1.200 pieces	200 pieces
BA19330	190 MM. X 330 MM.	1.200 pieces	200 pieces
BA19400	190 MM. X 400 MM.	1.200 pieces	200 pieces
BA30370	300 MM. X 370 MM.	800 pieces	200 pieces
BA30450	300 MM. X 450 MM.	800 pieces	200 pieces
BA30500	300 MM. X 500 MM.	800 pieces	200 pieces

*Other measures available on request

BP - STERIPERFECT FLAT POUCHES

REF	DIMENSIONS	PACKAGING
BP7520	75 MM. X 200 MM.	2.000 pieces
BP7525	75 MM. X 250 MM.	2.000 pieces
BP7530	75 MM. X 300 MM.	2.000 pieces
BP7545	75 MM. X 450 MM.	2.000 pieces
BP1015	100 MM. X 150 MM.	2.000 pieces
BP1020	100 MM. X 200 MM.	2.000 pieces
BP1025	100 MM. X 250 MM.	2.000 pieces
BP1030	100 MM. X 300 MM.	2.000 pieces
BP1035	100 MM. X 350 MM.	2.000 pieces
BP1040	100 MM. X 400 MM.	2.000 pieces
BP1055	100 MM. X 550 MM.	2.000 pieces
BP1220	120 MM. X 200 MM.	1.000 pieces
BP1520	150 MM. X 200 MM.	1.000 pieces
BP1525	150 MM. X 250 MM.	1.000 pieces
BP1530	150 MM. X 300 MM.	1.000 pieces
BP1535	150 MM. X 350 MM.	1.000 pieces
BP1540	150 MM. X 400 MM.	1.000 pieces
BP1622	160 MM. X 225 MM.	1.000 pieces
BP1635	160 MM. X 350 MM.	1.000 pieces
BP2025	200 MM. X 250 MM.	1.000 pieces
BP2030	200 MM. X 300 MM.	1.000 pieces
BP2035	200 MM. X 350 MM.	1.000 pieces
BP2040	200 MM. X 400 MM.	1.000 pieces
BP2050	200 MM. X 500 MM.	1.000 pieces

REF	DIMENSIONS	PACKAGING
BP2128	210 MM. X 280 MM.	1.000 pieces
BP2530	250 MM. X 300 MM.	1.000 pieces
BP2535	250 MM. X 350 MM.	1.000 pieces
BP2540	250 MM. X 400 MM.	1.000 pieces
BP2545	250 MM. X 450 MM.	1.000 pieces
BP2550	250 MM. X 500 MM.	1.000 pieces
BP2745	270 MM. X 450 MM.	1.000 pieces
BP3040	300 MM. X 400 MM.	1.000 pieces
BP3050	300 MM. X 500 MM.	1.000 pieces
BP3055	300 MM. X 550 MM.	1.000 pieces
BP3057	300 MM. X 570 MM.	1.000 pieces
BP3250	320 MM. X 500 MM.	500 pieces
BP3260	320 MM. X 600 MM.	500 pieces
BP3550	350 MM. X 500 MM.	500 pieces
BP3658	360 MM. X 580 MM.	500 pieces
BP4050	400 MM. X 500 MM.	500 pieces
BP4055	400 MM. X 550 MM.	500 pieces
BP4060	400 MM. X 600 MM.	500 pieces
BP4250	420 MM. X 500 MM.	500 pieces
BP4260	420 MM. X 600 MM.	500 pieces
BP5060	500 MM. X 600 MM.	500 pieces
BP6060	600 MM. X 600 MM.	500 pieces

*Other measures are available on request

Pouches are strapped in bats of 200/250 pieces.

LABELS

Each carton is equipped with a label, printed according to the normatives UNI CEI EN ISO 15223-1:2012 and UNI EN 1041:2013, containing all the information as per ISO 11607 series and UNI EN 868-5:2009.

LIMITATION OF USE

STERIDIAMOND - STERIPERFECT products are not suitable neither for dry heat sterilization nor for gas plasma sterilization.

WARNING

Weld the open side of the pouches and rolls with a heat sealer at the recommended temperature of 160-180 °C; such temperature can vary depending on contact time and welding speed of the heat sealer. Follow the instructions of the heat sealer manufacturer.

PRODUCT SHELF-LIFE

The product has a 5 years shelf-life from production date.

COMPLIANCE TO DIRECTIVES

Sterilization pouches and rolls are manufactured in compliance with the following regulations:

- ❖ MDD 93/42;
- ❖ UNI CEI EN ISO 14971: 2012 « Application of risks management of medical devices »;
- ❖ ISO 11607 standards;
- ❖ EN 868 standards – Packaging for medical devices terminally sterilized – part 3: paper to be used in the manufacturing of paper pouches (specified in the EN 868-4) and in the manufacturing of pouches and rolls (specified in the EN 868-5) - requirements and test methods;
- ❖ UNI EN ISO 11140-1:2014; “Sterilization of healthcare products – Chemical Indicators – Part 1: general requirements”
- ❖ UNI EN ISO 15882:2009 “Sterilization of healthcare products – Chemical Indicators – Guidelines for the selection, use and interpretation of results”;

PROCEDURES FOR CERTIFICATION

Annex VII of MDD 93/42.

Refer to the responsibility management included in the “Declaration of conformity”.

In witness
E.C.S. S.r.l.
General Manager
IVANO REDAELLI

FILM

PRODUCT DESCRIPTION: the coupled film PET/PP GREEN or BLUE is composed of a polyester layer and a polypropylene one.

APPLICATION FIELD: the coupled film PET/PP GREEN or BLUE has been specifically designed for the application with disposal medical devices and for the use with hot welding units.

The coupled film PET/PP GREEN or BLUE is suitable to be welded with medical paper, in order to be used for STEAM, EO and FORM sterilization and in order to be perfectly peelable during opening.

TRACEABILITY: the documentation concerning the materials used for the manufacturing of our products will be held at disposal during a period of five years starting from the manufacturing batch

WASTE-DISPOSAL: the coupled film PET/PP GREEN or BLUE is considered as a normal urban waste (in small quantities) and a special waste (in big quantities).

MEDICAL PAPER

STANDARDS COMPLIANCE:	conforms to EN 868 - Packaging for medical devices terminally sterilized – part 3: paper to be used in the manufacturing of paper pouches (specified in the EN 868-4) and in the manufacturing of pouches and rolls (specified in the EN 868-5) - requirements and test methods
PRODUCT DESCRIPTION:	medical paper 60 g/sqm is moisture-resistant and manufactured with 100% pure pulp. This paper grants a high resistance during opening and avoids the release of fiber during peeling. The paper porosity has been specifically designed for STEAM/EO/FORM sterilization and represents a reliable barrier against any bacteria.
APPLICATION:	medical paper 60 g/sqm is particularly designed for the production of pouches and rolls, printed or blank, where the paper is hot welded together with a coupled layer made of polyester and polypropylene film. The obtained product is suitable for STEAM/EO/FORM sterilization.
TRACEABILITY:	the documentation concerning the materials used for the manufacturing of our products will be held at disposal during a period of five years starting from the manufacturing batch
DISPOSAL:	the paper is considered as a normal urban waste (in small quantities) and a special waste (in big quantities).

DECLARATION OF CE CONFORMITY

In compliance with Annex VII, European Directive 93/42/CEE and further modifications and integrations, such as those provided by DL n. 37 of 25/01/2010, acknowledging the European Directive 2007/47/CE.

E.C.S. S.r.l.
Via I° Maggio, 18/22
23881 Airuno (LC)
Italy

Declares under its own responsibility that the products, designed as:

“STERIDIAMOND - STERIPERFECT FLAT ROLLS, GUSSETED ROLLS, FLAT POUCHES, GUSSETED POUCHES, SELF-SEALING POUCHES for STEAM, EO and FORM sterilization” satisfy all the requirements applicable to European Directive 93/42/CEE and further modifications such as those provided by the DL n. 37 of 25/01/2010, acknowledging the European Directive 2007/47/CE, concerning the medical devices and are registered to the Italian Ministry of Health.

“STERIDIAMOND - STERIPERFECT FLAT ROLLS, GUSSETED ROLLS, FLAT POUCHES, GUSSETED POUCHES, SELF-SEALING POUCHES for STEAM, EO and FORM sterilization” are made under DIN 59953 standard.

For this purpose, E.C.S. S.r.l. grants and declares under its own responsibility that:

- The range of the products referred to subject satisfies the essential requirements as per Annex I of the European Directive 93/42/CEE and further modifications such as those provided by the DL n. 37 of 25/01/2010, acknowledging the European Directive 2007/47/CE;
- The range of the products referred to subject belongs to Class I – non sterile;
- The devices referred to subject are not measurement instruments;
- The devices referred to subject are not designed for clinical trials purposes;
- The devices referred to subject comply to the European standards provided by UNI EN ISO 11607-1/-2 and UNI EN 868 - Packaging for medical devices terminally sterilized – part 3: paper to be used in the manufacturing of paper pouches (specified in the EN 868-4) and in the manufacturing of pouches and rolls (specified in the EN 868-5) - requirements and test methods
- ECS Srl, manufacturer of these products, is certified according to the rules UNI EN ISO 9001:2008 and UNI EN ISO 13485:2012.

E.C.S. S.r.l. declares that the documentation according to the Annex VII of the European Directive 93/42/CEE and further modifications such as those provided by the DL n. 37 of 25/01/2010, acknowledging the European Directive 2007/47/CE, will be held at disposal during a period of five years starting from the last manufacturing batch of the devices referred to subject.

Airuno, December 2017

In witness
E.C.S. S.r.l.
General Manager
IVANO REDAELLI