Product Dossier:

ANAESTHESIA SETS

/Epidural anaesthesia set advanced; Epidural anaesthesia set small; Combined anaesthesia set advanced; Combined anaesthesia set small; Epidural anaesthesia set with accessories for spinal and combined anaesthesia; Tuohy needle; Epidural catheter/

Class III

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1. PRODUCT SPECIFICATION

1.1. Product description

Anaesthesia sets manufactured by Balton company are available in type: combined anaesthesia set small, combined anaesthesia advanced, epidural anaesthesia set small, epidural anaesthesia set advanced, epidural anaesthesia set with accessories for spinal and combined anaesthesia.

The type and series of the products

Product type according CE certificate and intended purpose	**Type**	**Model**
Anaesthesia sets / Epidural anaesthesia sets are intended for the introduction of analgetic agents or opiate	Epidural anaesthesia set small	**ZZOMA,** **ZZOMAS, ZZOMASN, ZZOMASSN,** **ZZOMAEM, ZZOMASEM,** **ZZOMASNEM, ZZOMASSNE** *Where:* ***A** - size (16G; 17G; 18G; 19G)* ***S** - soft tip* ***SN** - low resistance siringe* ***EM** - catheter fixing element*
	Epidural anaesthesia set advanced	**ZZORA,** **ZZORAS,** **ZZORAEM,** **ZZORASEM** *Where:* ***A** - size (16G; 17G; 18G; 19G)* ***S** - soft tip* ***EM** - catheter fixing element*
	Combined anaesthesia set advanced	**ZZORAIB,** **ZZORASIB** **ZZORAIBEM,** **ZZORASIBEM** *Where:* ***A** - size (16G; 18G)* ***S** - soft tip* ***B** - spinal needle size and length* *(IPPS26G / 130;* *IPPS 26G / 90;* *IPPW 26G / 90;* *IPPS 27G / 130;* *IPPS 27G / 120;* *IPPS 27G / 90; IPPW27G / 120; IPPW27G / 90;* *IPPS26G / 130; IPPS26G / 90; IPPW26G / 90; IPPS27G / 130;* *IPPS27G / 120; IPPS27G / 90; IPPW27G / 120; IPPW27G / 90)*
	Combined anaesthesia set small	**ZZKA** *Where:* ***A** - size (16G; 18G)*

	Epidural anaesthesia set with accessories for spinal and combined anaesthesia	**ZZORAD, ZZORASD** *Where:* *A - size (18G; 19G; 20G; 22G)* *S - soft tip* *D - additional Elements* *(sterile field, bowl, gauze swab, tray, sponge, system for catheter fixing)*
	Tuohy needle	**ITA** *Where:* *A - size (16G; 17G; 18G; 19G)* *spinal needle length: 50mm, 80mm*
	Epidural catheter	**KEAS** *Where:* *A - size (18G; 19G; 20G; 22G)* *catheter length: from 90 to 105cm* *S - soft tip*

1.2. *Packaging conditions*

Conditions and types of packaging for anaesthesia sets:

Epidural anaesthesia sets (small; advanced) and Combined anaesthesia set advanced –are packed in sterile single use packing. Each set is placed respectively in polyvinyl chloride form made of hard foil. Then the hard foil is welded with a medical paper with inscriptions and then each single set is placed into cardboard box with the instruction for use. The unit packs are placed into white boxes and then into a collecting pack made of cardboard resistant to mechanical damage and stuck with tape that makes it impossible to open the box without damaging it. An individual unit packaging is then put in a bulk packaging – a collecting cardboard. The labels are affixed to the singe use packaging, cardboard box and collecting cardboard.

Epidural anaesthesia sets with accessories for spinal and combined anaethesia - are packed in sterile single use packing. Each set is placed on tray in the middle of the unfolding field then the set is packed on the Tyvek pouch. The unit packs are placed into white boxes and then into a collecting pack made of cardboard resistant to mechanical damage and stuck with tape that makes it impossible to open the box without damaging it. An individual unit packaging is then put in a bulk packaging – a collecting cardboard. The labels are affixed to the singe use packaging, cardboard box and collecting cardboard.

Combined anaesthesia set small – are packed in sterile single use packing. Each set is placed on paper-foil sleeve and then each single set is placed into cardboard box with the instruction for use. The unit packs are placed into white boxes and then into a collecting pack made of cardboard resistant to mechanical damage and stuck with tape that makes it impossible to open the box without damaging it. An individual unit packaging is then put in a bulk packaging – a collecting cardboard. The labels are affixed to the singe use packaging, cardboard box and collecting cardboard.

Tuohy needles– are packed into a single package for single use, namely into a paper-foil cuff. Single packages are packed into white boxes and then into collective packaging, namely cartons.

Epidural catheters– are packed into a single package for single use, namely into the pouch. Single packages are packed into white boxes and then into collective packaging, namely cartons.

1.3. Indications for use

Epidural anesthesia sets are intended for the introduction of analgetic agents or opiates. Epidural analgesia may be used:

- for analgesia alone (e.g. in childbirth);
- as an adjunct to general anesthesia. This is applicable for a wide variety of surgeries, e.g. hysterectomy, hip replacement, laparotomy or even open aortic aneurysm repair;
- as a sole technique for surgical anesthesia (e.g. Caesarean section);
- for post-operative or post-traumatic analgesia.

1.4. Contraindications

- allergy to the anesthetic drug
- anatomical abnormalities (e.g. spina bifida, scoliosis)
- bleeding disorder (coagulopathy) or anticoagulant medications (e.g. acenocumarol, warfarin, dabigatran, apixaban, rivaroxaban)
- systemic infection (sepsis)
- infection near the place of intended insertion
- lack of patient informed consent
- lack of cooperation with the patient
- neurological or neuromuscular disorders
- previous spinal surgery (scar tissue may impair the spread of the drug, or may cause an acquired tethered spinal cord)
- severe aortic stenosis or serious congenital heart disease
- uncorrected hypovolemia
- untreated arterial hypertension

1.5. Complications

Known complications include, in particular:

- abduscens palsy
- achievement of only partial analgesia or anesthesia (~ 15% of cases)
- arachnoiditis
- back pain
- breakage of the catheter or the needle
- cardiac arrest
- cauda equina injury
- cerebral herniation
- death

- epidermoid tumor development in long-term observation
- epidural abscess formation
- epidural hematoma
- hypotension
- incorrect insertion path
- infection at puncture site
- intercostal nerve paralysis
- meningitis
- paraplegia
- postpuncture headache
- puncture and injection to the blood vessel
- radicular pain or numbness
- septic infection
- spinal canal hematoma
- total spinal anesthesia

1.6. Precautions

- Tuohy needle should be always introduced with mandarin.
- Needles and single – use knives for skin incision are designed for single use only; do not re-sterilize.
- Decision to carry out the puncture procedure depends on the consent of the physician performing the procedure.
- Do not withdraw the catheter through the needle when it was introduced beyond the beheading of the needle because it threatens to cut off the tip of the catheter.
- Product for single use only.
- Product is not suitable to be re-sterilization.
- Do not use if the package is open for damaged.
- One should remember about EtO residues.
- Do not use after the expiry date stated on the label.
- Store in a dry place, at the temperature of 10 – 30 ºC.

1.7. Instructions for use

An instruction is enclosed with each individual packaging.

2. SPECIFICATION OF RAW MATERIALS

2.1. Product composition

2.1.1. Anaesthesia set. Epidural anaesthesia set, advanced – **ZZOR, ZZOR_S**

No	INTERMEDIATE PRODUCTS	RAW MATERIAL
1.	catheter tube	polyamide, bismuth,
2.	basis cap	homopolimer acetal

	flap of cap	
3.	tube of cap the epidural catheter	thermoplastic elastomer
4.	soft tube	polyamide, bismuth,
5.	Luer- lock plug	polyethylene
6.	needle for anaesthesia	finished product
7.	needle for drug administration	finished product
8.	scarifier	finished semi-product
9.	scarifier casing	polyethylene
10.	scarifier cap	polycarbonate
11.	Touhy needle tube	Stainless steel
12.	butterfly	Polypropylene
13.	pivot	Polyamide
14.	cap	polycarbonate
15.	luer cap	copolymer
16.	Touhy needle casing	Polypropylene
17.	Tuohy needle 19G	finished product
18.	Syringe 10 ml	finished product
19.	low resistance syringe body	polypropylene
20.	low resistance syringe pusher	polypropylene
21.	low resistance syringe piston	finished product
22.	filter housing	polycarbonate
23.	filter casing	polycarbonate
24.	cartridge filter (0,2 µm pore size)	finished semi-product
25.	self-adhesive element for filter fixing	finished product
26.	element for catheter fixing	polycarbonate
27.	universal sleeve	polypropylene
28.	System for catheter fixing	Finished semi-product

2.1.2. Anaesthesia set. Epidural anaesthesia set small - **ZZOM, ZZOM_S, ZZOM_SN, ZZOM_SSN**

No	INTERMEDIATE PRODUCTS	RAW MATERIAL
1.	catheter tube	polyamide, bismuth
2.	basis cap flap of cap	homopolymer acetal
3.	tube of cap the epidural catheter	thermoplastic elastomer
4.	soft tube	Polyamide, Bismuth
5.	Luer- lock plug	polyethylene

6.	Touhy needle tube	Stainless steel
7.	butterfly	Polypropylene
8.	pivot	Polyamide
9.	cap	polycarbonate
10.	luer cap	copolymer
11.	Touhy needle casing	Polypropylene
12.	Tuohy needle 19G	finished product
13.	low resistance syringe body	polypropylene
14.	low resistance syringe pusher	polypropylene
15.	low resistance syringe piston	finished product
16.	filter housing	polycarbonate
17.	filter casing	polycarbonate
18.	cartridge filter (0,2 µm pore size)	finished semi- product
19.	self-adhesive element for filter fixing	finished product
20.	element for catheter fixing	polycarbonate
21.	universal sleeve	polypropylene
22.	System for catheter fixing	Finished semi-product

2.1.3. Anaesthesia set. Epidural anaesthesia set with accessories for spinal and combined anaethesia- **ZZOR_D, ZZOR_SD**

No	INTERMEDIATE PRODUCTS	RAW MATERIAL
1.	catheter tube	polyamide, bismuth
2.	basis cap flap of cap	homopolymer acetal
3.	tube of cap the epidural catheter	thermoplastic elastomer
4.	soft tube	Polyamide, Bismuth
5.	Luer- lock plug	polyethylene
6.	needle for anaesthesia	finished product
7.	needle for drug administration	finished product
8.	scarifier	finished semi-product
9.	scarifier casing	polyethylene
10.	scarifier cap	polycarbonate
11.	Touhy needle tube	Stainless steel
12.	butterfly	Polypropylene
13.	pivot	Polyamide
14.	cap	polycarbonate
15.	luer cap	copolymer
16.	Touhy needle casing	Polypropylene

17.	Tuohy needle 19G	finished product
18.	Syringe 10 ml	finished product
19.	low resistance syringe body	polypropylene
20.	low resistance syringe pusher	polypropylene
21.	low resistance syringe piston	finished product
22.	filter housing	polycarbonate
23.	filter casing	polycarbonate
24.	cartridge filter (0,2 µm pore size)	finished semi-product
25.	self-adhesive element for filter fixing	finished product
26.	element for catheter fixing	polycarbonate
27.	universal sleeve	polypropylene
28.	tray	finished product
29.	gauze swab (72,5x90) gauze swab (55x60) gauze swab (55x60)-with hole and adhesive tape	finished product
30.	Bowl 60ml	finished product
31.	Syringe 5ml	finished product
32.	Syringe 3 ml	finished product
33.	guiding needle 22Gx38mm	finished product
34.	spinal needle 27Gx90 mm	finished product
35.	injection needle 18G, 22G	finished product
36.	filter needle 18Gx40mm, 5µm	finished product
37.	gauze swab 10x10cm gauze swab 7,5x7,5cm	finished product
38.	sponge stick	finished product
39.	System for catheter fixing	finished products

2.1.4. Anaesthesia set. Combined anaesthesia set advanced - **ZZOR_I, ZZOR_SI_**

No	INTERMEDIATE PRODUCTS	RAW MATERIAL
1.	catheter tube	polyamide, bismuth
2.	basis cap flap of cap	homopolimer acetal
3.	tube of cap the epidural catheter	thermoplastic elastomer
4.	soft tube	Polyamide, Bismuth
5.	Luer- lock plug	polyethylene

6.	needle for anaesthesia	finished product
7.	needle for drug administration	finished product
8.	scarifier	finished semi-product according Technological Instruction no LAJ-02
9.	scarifier casing	polyethylene
10.	scarifier cap	polycarbonate
11.	Touhy needle tube	Stainless steel
12.	butterfly	Polypropylene
13.	pivot	Polyamide
14.	cap	polycarbonate
15.	luer cap	copolymer
16.	Touhy needle casing	Polypropylene
17.	Syringe 10 ml	finished product
18.	low resistance syringe body	polypropylene
19.	low resistance syringe pusher	polypropylene
20.	low resistance syringe piston	finished product
21.	filter housing	polycarbonate
22.	filter casing	polycarbonate
23.	cartridge filter (0,2 µm pore size)	finished semi-product
24.	self-adhesive element for filter fixing	finished product
25.	element for catheter fixing	polycarbonate
26.	universal sleeve	polypropylene
27.	Spinal needles: IPPS26G130 IPPS26G90 IPPW26G90 IPPS27G130 IPPS27G120 IPPS27G90 IPPW27G120 IPPW27G90	finished products
28.	System for catheter fixing	finished products

2.1.5. Anaesthesia set. Combined anaesthesia set –small- **ZZK**

No	INTERMEDIATE PRODUCTS	RAW MATERIAL

1.	Touhy needle tube	Stainless steel
2.	butterfly	Polypropylene
3.	pivot	Polyamide
4.	cap	polycarbonate
5.	luer cap	copolymer
6.	Touhy needle casing	Polypropylene
7.	Spinal needles standard IPPS26G130	finished products

2.1.6. Tuohy needle

No	INTERMEDIATE PRODUCTS	RAW MATERIAL
1	Tuohy needle tube	Stainless Steel
2	cap	polycarbonate
3	pivot	Polyamide
4	butterfly	Polypropylene
5	Luer cap	copolymer
6	Touhy needle casing	Polypropylene
7	Tuohy needle 19G	finished products

2.1.7. Epidural catheter

No	INTERMEDIATE PRODUCTS	RAW MATERIAL
1	Catheter tube	Polyamide, radiopaque line
2	Soft tube (only for soft catheter)	Polyamide, bizmuth
3	The base of the cap	Polyoxymethylene
4	Flap cap	Polyoxymethylene
5	Luer-lock cap	Polyethylene
6	Tuber for the epidural catheter cap	Thermoplastic elastomer

2.2. Control characteristic

Polyamide, Polyethylene, Polypropylene, Polycarbonate, Copolymer, Stainless steel.
Finished product is controlled based on the manufacturer's certificate. Visual control, control of certificates.

2.3. *Information about suppliers*

The suppliers have been qualified in accordance with the EN ISO 13485 Standard, according to the procedures QP 7.4.1.; QP 7.4.3.

3. *PRODUCTION PROCESS SPECIFICATION*

Individual production stages are conducted in air – conditioned rooms with the air control in accordance with the ISO Class 8.

3.1. *Description of the manufacturing process*

The description of particular operations in the manufacturing process and measuring instruments used in the production is presented in the appropriate technical instructions for a given product. Productive operations are documented in the reports of product series.

Product symbol	No of raport series	No of technological instruction
ZZOR, ZZOR_S	BA 355	355
ZZOM, ZZOM_S, ZZOM_SN, ZZOM_SSN	BA 356	356
ZZOR_I /ZZOR_S_I	BA 357	357
ZZK	BA 358	358
ZZOR_D/ ZZOR_SD	BA 360	360
IT	BA 323	323
KE	BA 314	314

4. *PACKAGING AND LABELLING SPECIFICATION*

4.1. Packaging

Types of packaging for Anaesthesia sets:

Epidural anaesthesia sets (small; advanced) and Combined anaesthesia set advanced –are packed in sterile single use packing. Each set is placed respectively in polyvinyl chloride form made of hard foil. Then the hard foil is welded with a medical paper with inscriptions and then each single set is placed into cardboard box with the instruction for use. The unit packs are placed into white boxes and then into a collecting pack made of cardboard resistant to mechanical damage and stuck with tape that makes it impossible to open the box without damaging it. An individual unit packaging is then put in a bulk packaging – a collecting cardboard. The labels are affixed to the singe use packaging, cardboard box and collecting cardboard.

Epidural anaesthesia sets with accessories for spinal and combined anaethesia - are packed in sterile single use packing. Each set is placed on tray in the middle of the unfolding field then the set is packed on the Tyvek pouch. The unit packs are placed into white boxes and then into

a collecting pack made of cardboard resistant to mechanical damage and stuck with tape that makes it impossible to open the box without damaging it. An individual unit packaging is then put in a bulk packaging – a collecting cardboard. The labels are affixed to the singe use packaging, cardboard box and collecting cardboard.

Combined anaesthesia set small – are packed in sterile single use packing. Each set is placed on paper-foil sleeve and then each single set is placed into cardboard box with the instruction for use. The unit packs are placed into white boxes and then into a collecting pack made of cardboard resistant to mechanical damage and stuck with tape that makes it impossible to open the box without damaging it. An individual unit packaging is then put in a bulk packaging – a collecting cardboard. The labels are affixed to the singe use packaging, cardboard box and collecting cardboard.

Tuohy needles– are packed into a single package for single use, namely into a paper-foil cuff. Single packages are packed into white boxes and then into collective packaging, namely cartons.

Epidural catheters– are packed into a single package foe single use, namely into the pouch. Single packages are packed into white boxes and then into collective packaging, namely cartons.

Marking	**Composition**	**Norms and specifications**
Paper with inscriptions	Medical paper	PM/02/04
Form	PVC hard foil	FT/03/04
Paper	Intergrapeel DS. Medical Paper	FM/02/04
TYVEK pouch	Foil – paper	PT/06/13
Paper pouch	Foil – paper	PP/05/13
Box	Cardboard	HŻ/C/03002/09
Carton	Cardboard	ISO 4046-1-4:2002

4.2. Packaging machine

Welding foil blister with medical paper. The packing machine ILLIG HSP35/3 No 01-140-N.

Welding foil blister with medical paper. The packing machine ILLIG HSP35/2 No 01-317-N.

Sealing of the TYVEK pouch. The packing machine -Steriking RS120 No 01-143-N.

Sealing of the paper pouch. The packaging machine -Steriking RS120 No 01-072-N.

Sealing of the paper pouch. The packaging machine -Steriking RS120 No 01-541-N.

Welding paper with foil. Packaging machine Multivac type R70 No 01-078-N.

4.3. Packaging process

Epidural anaesthesia sets (small; advanced) and Combined anaesthesia set advanced

- preparation of ready kits products,

- placement of kit products into foil blister,
- welding foil blister with medical paper,
- sticking labels on single units,
- single units packing into the boxes,
- sticking labels on boxes,
- white boxes packing into the bulk cartons,
- sticking labels on bulk cartons.

Individual packaging is performed in compartments with air control under ISO Class 8 clean room conditions.
Collective packaging is performed in compartments without air control.

Epidural anaesthesia sets with accessories for spinal and combined anaethesia:

- preparation of ready kits products,
- placement of the product in foil pouch
- sealing of the pouch
- sticking labels on single units,
- packing unit packs into cardboard boxes
- packing cardboard boxes into the collective cardboard box
- sticking a label onto the cardboard.

Individual packaging is performed in compartments with air control under ISO Class 8 clean room conditions.
Collective packaging is performed in compartments without air control.

Combined anaesthesia set small:

- preparation of ready kits products,
- placement of the product in paper pouch
- sealing of the pouch
- sticking labels on single units,
- packing unit packs into cardboard boxes
- packing cardboard boxes into the collective cardboard box
- sticking a label onto the cardboard.

Individual packaging is performed in compartments with air control under ISO Class 8 clean room conditions.
Collective packaging is performed in compartments without air control.

Tuohy needle

- preparation of ready products
- placement the product into paper-foil cuff
- welding paper with foil
- sticking labels on single units,
- packing unit packs into cardboard boxes
- packing cardboard boxes into the collective cardboard box
- sticking a label onto the cardboard.

Individual packaging is performed in compartments with air control under ISO Class 8 clean room conditions.
Collective packaging is performed in compartments without air control.

Epidural catheter

- preparation of ready products
- placement the product into paper-foil cuff
- welding paper with foil
- sticking labels on single units,
- packing unit packs into cardboard boxes
- packing cardboard boxes into the collective cardboard box
- sticking a label onto the cardboard.

Individual packaging is performed in compartments with air control under ISO Class 8 clean room conditions.
Collective packaging is performed in compartments without air control.

4.4. Labels

The paper label stuck onto unit packs, white boxes and cardboard contains the following information in comply with EN 15223-1, EN 1041 Standards:

- product name,
- manufacturer's name, address and trade-mark,
- listed elements included in the kit,
- UDI code,
- LOT number,
- sterilization date: year, month,
- validity date (month, year),
- sterile, nontoxic, nonpyrogenic
- inscriptions:
    1. Do not use if package is damaged,
    2. Use only once,
    3. Store in room temperature,
    4. Store in a cool, dark, dry place,
    5. Nonpyrogenic, nontoxic, sterile,
    6. Consult instruction for use,
    7. Sterilized with ethylene oxide.

5. ***CONTROL SPECIFICATION***

5.1. Raw materials control

Control of materials is lead according to procedure QP 7.4.3.; visual control and certificates control.

5.2. Inter operational production control

- Checking dimensions,
- Checking appearance,
- Checking the quality of gluing,
- Checking the cleanliness and quality of the set elements,

Particular control stages have been presented in the technological instructions.

5.3. Control of impurities during the production process

The purity state of the products, at individual production stages before sterilisation, is controlled for individual product groups and is defined in the procedure QP 6.4. and the instruction
QI 6.4.1.

5.4. Packaging materials control

Conducted in accordance with procedure QP 7.4.3.

5.5. Packaging control

The control of single packages.
The control of welding integrity.
According to instruction QI 8.2.6.16

5.6. Final product control

5.6.1. Physical control

- checking the appearance and dimensions of set's elements,
- checking mechanical resistance,
- checking catheters cap,
- checking the filtration effectiveness,
- checking physical-mechanical properties of the needle,
- checking the needles resistance to corrosion
- checking the tightness of joints of particular catheter elements

Physical control is providing in comply with ISO 2859-1, ISO 7864, EN ISO 7886-1, ISO 6009, Standards and QI 8.2.6.14.; QI 8.2.6.16; QI 8.2.6.17.Instructions.

5.6.2. Pyrogens

Done by means of LAL test in compliance with instruction QI 8.2.6.3. in the microbiological laboratory of Balton company.

5.6.3. Sterility

Carried out according to the instruction QI 8.2.6.2. by Balton microbiological laboratory.

5.6.4. Biocompatibility

Performed by the National Medicines Institute, and by the CHSP Technochemia.

6. OBSERVANCE OF ENVIRONMENT CONDITIONS

6.1. Room and air control

According to the procedure QP 6.4. and the instruction QI 6.4.1.

- the control of overpressure in individual rooms,
- annual control or once the air particle filters have been changed, filter check,
- quarterly verification of the air supplying installation and air conditioning,
- bacteriological control of working rooms and air monitoring /instruction,
- quarterly control of water microbiological purity /instruction.

6.2. Personnel control

According to the procedure QP 6.4. and the instruction QI 6.4.1.

- the control of personnel hygiene in the rooms with controlled atmosphere,
- periodic medical checkups,
- the control of working clothing in the clean zone.

6.3. Content of microbiological impurities in the product prior to sterilization

According to the procedure QI 8.2.6.6.

7. STORING MAINTENANCE

7.1. Expiry date

For the Epidural Anesthesia sets sterilized with ethylene oxide expiry date are 4 years and 11 months from the day of sterilization.

7.2. Storing conditions

The products should be stored in a dry and cool place in the temperature of 100-300C according to the QP 7.5.11. Procedure.

7.3. STERILIZATION

It is carried out in accordance with the EN ISO 11135 Standards.
Sterilization with ethylene oxide is carried out in accordance with the instructions QI 7.5.1.2. and QI 7.5.1.3.

7.3.1. Sterilization conditions

Device type: the sterilizer of the Getinge GEE 14422 73 AR-2, sterilization conditions in accordance with the instruction QI 7.5.1.2.

Parameters:

a)	Conditioning parameters outside the chamber	min. 18°C
b)	Preliminary conditioning parameters:	
	Final conditioning period temperature	42 ± 3°C
	Relative humidity	50 - 90 %,
	Conditioning time	min. 8 hrs.,
	Pressure	0,75 - 0,95 bar,
c)	Sterilization process parameters:	
	Temperature in the chamber	42 ± 3°C,
	Relative humidity	50- 90 %
	Ethylene oxide concentration	0,6 - 0,8 kg/m^3
	Allowed S-90 gas quantity	16 kg -22 kg,
	S-90 gas quality	mixture of 90 % ETO + 10 % CO_2
	Exposure time	220± 5 min
	Sterilization time	320 ± 5 min
	Preliminary pressure	0,08 bar
	Pressure following introduction of ethylene oxide	min. 0,50+/- 0,05 bar
	Working pressure	min. 0,9 ± 0,01 bar
d)	Sterilization material degasification process parameters:	
	Pressure value in sterilization chamber before gas evacuation	0.90 +/- 0,05 bar
	Pressure value following gas evacuation	0,14 +/- 0,05 bar
	Final pressure value	1 bar
	Gas evacuation time	99-110 min.
	Number of run-purge	5 x
e)	Quarantine process parameters:	
	Desorption time	min. 7 days
	Number of air exchange counts in quarantine	min. 10
	Desorption temperature	18-30°C in the room

7.3.2. The control of sterilization effectiveness

7.3.1. <u>The control of sterilization effectiveness</u>

The results of the process qualification including physical qualification (PPQ) and microbiological qualification (MPQ) confirmed the effectiveness of the sterilization process.
After properly carrying out the sterilization process, we will obtain a sterile product with the required level of probability equal to or less than: 10·6 of finding one CFU (Colony Forming Unit) in a million sterilized products.
If it is necessary to introduce changes to the validated process, it is necessary to launch the P01QP5 "Change Control" procedure. In the case of implementing significant changes that may affect the validation status, the process should be revalidated on an ad hoc basis (to the

extent justified).
In accordance with the instruction I1P01QP7 "Validation of the sterilization process with ethylene oxide", the sterilization process efficiency should be reviewed annually, and the planned, periodic process validation should take place no later than: within 2 flights from the date of completion of this validation.

7.3.3. Routine controls.

- After the validation is completed, the routine sterilization process is carried out and controlled according to internal instruction.