

DATE	1.12.2023
DOC.NO	TDS003
PAGE NO	1
REV.NO	
REV.DATE	

TECHNICAL DATA SHEET

PRODUCT: Sterile Surgical Field

Description of Product:	Sterile Surgical Field / 50x40 cm
Raw Materials:	LSP2
Product Colour:	Medical Blue
Reference Code:	HD03009001
Weight in Grams:	56 gsm
Package:	Flat Pouch

Product: MDR Manufactured in accordance with (EU) 2017 / 745 Annex XI Part A. Products and materials used do not contain metal.

Technical Documentation

Technical Drawing

CERTIFICATES

EC CERTIFICATE (CE 2696)
ISO 13485:2016
MDR (EU) 2017/745

STANDARDS

EN ISO 13485	EN ISO 10993-10
EN ISO 11135	ISO 11737-1
EN ISO 13795-1	EN ISO 1041
EN ISO 15223-1	EN ISO 11807
EN ISO 14698-1	EN ISO 14001
EN ISO 10993-1	EN ISO 9001
EN ISO 14971:2019	
EN ISO 14698-2	
EN ISO 10993-5	



INSTRUCTION FOR USAGE

It is used to prevent infections by creating a barrier between sterile and non-sterile areas.

EXPIRY DATE

5 YEAR SHELF LIFE

Label Information

All sizes have % 2 cm tolerance

Package Information

- Article number,
- Lot number,
- Manufacturer,
- Production date,
- Expiry date,
- Single use,
- CE Mark
- Other customer requests

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into MHK's standard sized carton; dimensions are as follows:
Height = 45 cm; Length = 60 cm ve Width = 40 cm.

TECHNICAL DATA SHEET

PRODUCT: Sterile Subclavian Set

Description of Product:	Sterile Subclavian Set
Raw Materials:	LSP2
Product Colour:	Medical Blue
Reference Code:	HP03005004
Weight in Grams:	56 gsm
Package:	Flat Pouch

Product: MDR Manufactured in accordance with (EU) 2017 / 745 Annex XI Part A. Products and materials used do not contain metal.

Technical Documentation

Technical Drawing

CERTIFICATES

EC CERTIFICATE (CE 2696)
ISO 13485:2016
MDR (EU) 2017/745

STANDARDS

EN ISO 13485	EN ISO 10993-10
EN ISO 11135	ISO 11737-1
EN ISO 13795-1	EN ISO 1041
EN ISO 15223-1	EN ISO 11807
EN ISO 14698-1	EN ISO 14001
EN ISO 10993-1	EN ISO 9001
EN ISO 14971:2019	
EN ISO 14698-2	
EN ISO 10993-5	

INSTRUCTION FOR USAGE

It is used to prevent infections by creating a barrier between sterile and non-sterile areas.

EXPIRY DATE

5 YEAR SHELF LIFE

Sterile Subclavian Set

1	Absorbent field with adhesive device 45x75 (with hole).
2	Absorbent field 75 x 90 (with hole)
3	Busturium N 11
4	Bowl - 2 pieces, volume 60 ml.
5	Plantain 2 pieces.
6	Kocher forceps 13 cm 1 piece
7	Absorbent pad 10x10cm 10 pieces
8	Absorbent pad 7.5x7.5cm 10 pieces

45x75 cm	LSP2	1
75x90 cm	LSP2	1
No.11	**	1
60 ml	**	2
ST	**	2
13 cm	**	1
10x10 cm	NW	10
7.5x7.5 cm	NW	10



Label Information

All sizes have % 2 cm tolerance

Package Information

- Article number,
- Lot number,
- Manufacturer,
- Production date,
- Expiry date,
- Single use,
- CE Mark
- Other customer requests

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into MHK's standard sized carton; dimensions are as follows:
Height = 45 cm; Length = 60 cm ve Width = 40 cm.

TECHNICAL DATA SHEET

PRODUCT: Sterile Pericardiocentesis Set

Description of Product:	Sterile Pericardiocentesis Set
Raw Materials:	LSP2
Product Colour:	Medical Blue
Reference Code:	HP03005003
Weight in Grams:	56 gsm
Package:	Flat Pouch

Product: MDR Manufactured in accordance with (EU) 2017 / 745 Annex XI Part A. Products and materials used do not contain metal.

Technical Documentation

EC CERTIFICATE (CE 2696)
ISO 13485:2016
MDR (EU) 2017/745

EN ISO 13485	EN ISO 10993-10
EN ISO 11135	ISO 11737-1
EN ISO 13795-1	EN ISO 1041
EN ISO 15223-1	EN ISO 11807
EN ISO 14698-1	EN ISO 14001
EN ISO 10993-1	EN ISO 9001
EN ISO 14971:2019	
EN ISO 14698-2	
EN ISO 10993-5	

Technical Drawing

Sterile Pericardiocentesis Set

1	Field for the table 75x100cm-1pc.	75x100 cm	Pe*NW	1
2	Sterile field 75x90cm with aperture - 1pc.	75x90 cm	LSP2	1
3	Sterile field 75x90cm - 1 pc	75x90 cm	LSP2	1
4	Bliester 27x13cm with 4 cavities. 1700ml.	27x13 cm	**	1
5	Absorbent pad 5x5cm - 10 pcs	5x5 cm	NW	10
6	Applicator 15cm - 2 pcs	15 cm	**	2
7	Bowl 60ml made of polypropylene, graduated, transparent - 1 pc	60 ml	**	1
8	Needle 18G 70mm - 1pc	18G 70 mm	**	1



INSTRUCTION FOR USAGE
It is used to prevent infections by creating a barrier between sterile and non-sterile areas.

EXPIRY DATE
5 YEAR SHELF LIFE

Label Information

- Article number,
- Lot number,
- Manufacturer,
- Production date,
- Expiry date,
- Single use,
- CE Mark
- Other customer requests

All sizes have % 2 cm tolerance

Package Information

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into MHK's standard sized carton; dimensions are as follows:
Height = 45 cm; Length = 60 cm ve Width = 40 cm.

TECHNICAL DATA SHEET

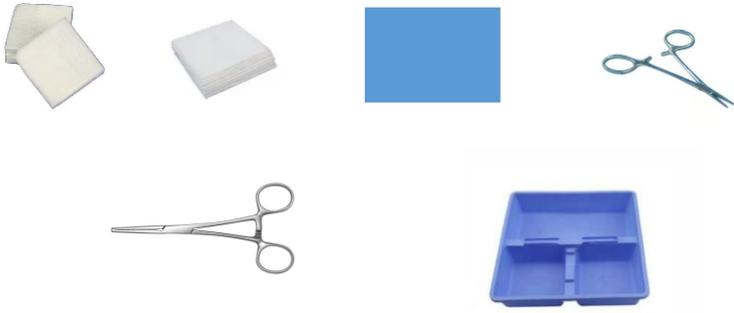
PRODUCT: Sterile Disposable Set

Description of Product:	Sterile Disposable Set
Raw Materials:	LSP2
Product Colour:	Medical Blue
Reference Code:	HP03009002
Weight in Grams:	56 gsm
Package:	Flat Pouch

Product: MDR Manufactured in accordance with (EU) 2017 / 745 Annex XI Part A. Products and materials used do not contain metal.

Technical Documentation

Technical Drawing

CERTIFICATES	EC CERTIFICATE (CE 2696) ISO 13485:2016 MDR (EU) 2017/745	<table border="1"> <thead> <tr> <th colspan="4">Sterile Personal Disposable Set</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>5 pcs.: Absorbent pad 5x5 cm</td> <td>5x5 cm</td> <td>NW</td> <td>5</td> </tr> <tr> <td>2</td> <td>5 pcs.: Absorbent pad 10x10 cm</td> <td>10x10 cm</td> <td>NW</td> <td>5</td> </tr> <tr> <td>3</td> <td>1 pc.: Sterile field 40x50 cm</td> <td>40x50 cm</td> <td>LSp2</td> <td>1</td> </tr> <tr> <td>4</td> <td>1 pc.: Forceps 13 cm</td> <td>13 cm</td> <td>**</td> <td>1</td> </tr> <tr> <td>5</td> <td>1 pc.: Kohler forceps 14 cm</td> <td>14 cm</td> <td>**</td> <td>1</td> </tr> <tr> <td>6</td> <td>1 pc.: Applicator 12 cm</td> <td>12 cm</td> <td>**</td> <td>1</td> </tr> <tr> <td>7</td> <td>1 pc.: Blister 22x20 cm with 5 cavities</td> <td>22x20 cm</td> <td>**</td> <td>1</td> </tr> </tbody> </table>			Sterile Personal Disposable Set				1	5 pcs.: Absorbent pad 5x5 cm	5x5 cm	NW	5	2	5 pcs.: Absorbent pad 10x10 cm	10x10 cm	NW	5	3	1 pc.: Sterile field 40x50 cm	40x50 cm	LSp2	1	4	1 pc.: Forceps 13 cm	13 cm	**	1	5	1 pc.: Kohler forceps 14 cm	14 cm	**	1	6	1 pc.: Applicator 12 cm	12 cm	**	1	7	1 pc.: Blister 22x20 cm with 5 cavities	22x20 cm	**	1
	Sterile Personal Disposable Set																																										
1	5 pcs.: Absorbent pad 5x5 cm	5x5 cm	NW	5																																							
2	5 pcs.: Absorbent pad 10x10 cm	10x10 cm	NW	5																																							
3	1 pc.: Sterile field 40x50 cm	40x50 cm	LSp2	1																																							
4	1 pc.: Forceps 13 cm	13 cm	**	1																																							
5	1 pc.: Kohler forceps 14 cm	14 cm	**	1																																							
6	1 pc.: Applicator 12 cm	12 cm	**	1																																							
7	1 pc.: Blister 22x20 cm with 5 cavities	22x20 cm	**	1																																							
STANDARDS	<table border="0"> <tr> <td>EN ISO 13485</td> <td>EN ISO 10993-10</td> </tr> <tr> <td>EN ISO 11135</td> <td>ISO 11737-1</td> </tr> <tr> <td>EN ISO 13795-1</td> <td>EN ISO 1041</td> </tr> <tr> <td>EN ISO 15223-1</td> <td>EN ISO 11807</td> </tr> <tr> <td>EN ISO 14698-1</td> <td>EN ISO 14001</td> </tr> <tr> <td>EN ISO 10993-1</td> <td>EN ISO 9001</td> </tr> <tr> <td>EN ISO 14971:2019</td> <td></td> </tr> <tr> <td>EN ISO 14698-2</td> <td></td> </tr> <tr> <td>EN ISO 10993-5</td> <td></td> </tr> </table>	EN ISO 13485	EN ISO 10993-10	EN ISO 11135	ISO 11737-1	EN ISO 13795-1	EN ISO 1041	EN ISO 15223-1	EN ISO 11807	EN ISO 14698-1	EN ISO 14001	EN ISO 10993-1	EN ISO 9001	EN ISO 14971:2019		EN ISO 14698-2		EN ISO 10993-5																									
EN ISO 13485	EN ISO 10993-10																																										
EN ISO 11135	ISO 11737-1																																										
EN ISO 13795-1	EN ISO 1041																																										
EN ISO 15223-1	EN ISO 11807																																										
EN ISO 14698-1	EN ISO 14001																																										
EN ISO 10993-1	EN ISO 9001																																										
EN ISO 14971:2019																																											
EN ISO 14698-2																																											
EN ISO 10993-5																																											
INSTRUCTION FOR USAGE	It is used to prevent infections by creating a barrier between sterile and non-sterile areas.																																										
EXPIRY DATE	5 YEAR SHELF LIFE																																										

Label Information

All sizes have % 2 cm tolerance

Package Information

- Article number,
- Lot number,
- Manufacturer,
- Production date,
- Expiry date,
- Single use,
- CE Mark
- Other customer requests

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into MHK's standard sized carton; dimensions are as follows:
Height = 45 cm; Length = 60 cm ve Width = 40 cm.