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TECHNICAL DATA SHEET

BD MaxZero™ extension set with needle-free connector Microbore

PVC, DEHP, natural rubber Latex are not part of the material formulation
Sterile, for Single Use

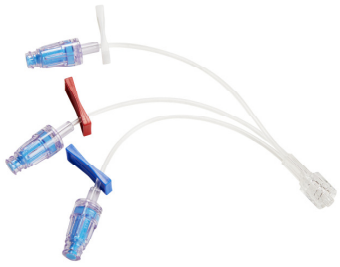
Product references presented in this technical data sheet:
MFX2601MZ, MFX2602MZ, MFX2603MZ

1. General Information

1.1 General

The sets in this technical data sheet belong to Intravenous Administration Sets for General Purpose. They are multiway extension sets with microbore of internal diameter of 1 mm and external diameter of 2,1 mm. The intended use is infusion.

BD MaxZero™ extension set with needle-free connector contains a flexible microbore tube with slide clamp, male luer lock at one side and additional feature, needle-free connector BD MaxZero™ at the other.



There are three types of BD MaxZero™ extension sets with needle-free connector comprised in this technical data sheet:

1) 1-way extension set, model MFX2601MZ, that contains 1 needle-free connector
2) 2-way extension set, model MFX2602MZ, that contains 2 needle-free connectors and 2 slide clamps in different colors (white and blue) to distinguish the 2 lines
3) 3-way extension set, model MFX2603MZ, that contains 3 needle-free connectors and 3 slide clamps in different colors (white, blue and red) to distinguish the 3 lines.

BD MaxZero™ extension set with needle-free connector, Microbore, version January 2018

PRODUCT REFERENCE	PRODUCT DESCRIPTION	TUBE LENGTH in cm	TOTAL LENGTH in cm	BOX (UNITS)
MFX2601MZ	Extension set with MaxZero™ connector, microbore, 1 clamp	12	17	50/150
MFX2602MZ	2-way extension set with 2 MaxZero™ connectors, microbore, 2 clamps	12	17	50/150
MFX2603MZ	3-way extension set with 3 MaxZero™ connectors, microbore, 3 clamps	12	17	50/150

Further Features

PRODUCT REF.	GRAVITY USE Max. Flow Rate	PRESSURE	VENTED SPIKE	BCV	ANTI-SYPHON VALVE	NFC MaxZero ™	FILTER SIZE	CHANGE INTERVAL	LIPID RESIST.
MFX2601MZ	Yes; 12ml/min*	2,5 bar	no	no	no	Yes, 1	no	According to the facility protocol**	yes
MFX2602MZ	Yes; 25ml/min*	2,5 bar	no	no	no	Yes, 2	no	According to the facility protocol**	yes
MFX2603MZ	Yes; 32ml/min*	2,5 bar	no	no	no	Yes, 3	no	According to the facility protocol**	yes

*) Test performed to measure maximum flow rate: an infusion bag filled with water hangs at 100cm height. An IV line connected goes to the input from the system. The flow is measured within a minute.
**) Change according to the facility protocol or in accordance with current recognized guidelines for IV therapy such as every 7 days or 200 activations

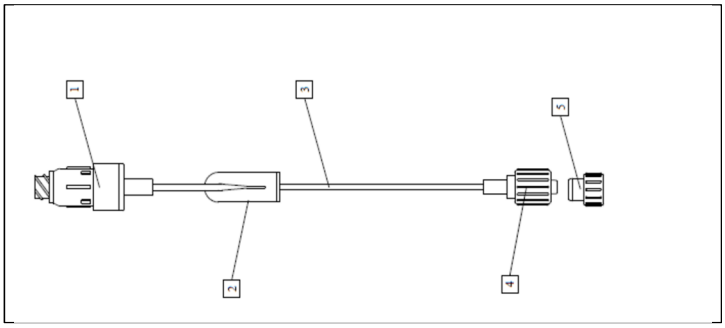
1.2 Certification

PRODUCT REF.	LEGAL MANUF.	MFG. SITE	ISO CERT.NO.	NOT. BODY	EC CERT.NO.	EU AUTHOR. REP.	COUNTRY OF ORIGIN
MFX2601MZ MFX2602MZ MFX2603MZ	Impromedifor m, Gielster Stück 11, 58513 Lüdenscheid, Germany	Metallform (Malta) ltd. HF64. Hal Far Industrial Estate. B'bugia BBG 3000, Malta	Registered under: Z/16/0393 2E Report Number 179-16-32	ECM GmbH, 0481	Registered under: Z/13/03230 Report Number 179-13-220	N/A	Malta

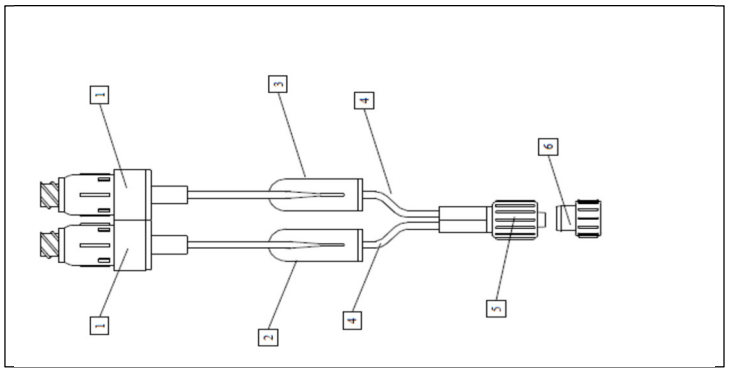
BD MaxZero™ extension set with needle-free connector, Microbore, version January 2018

1.3 Material and product configuration

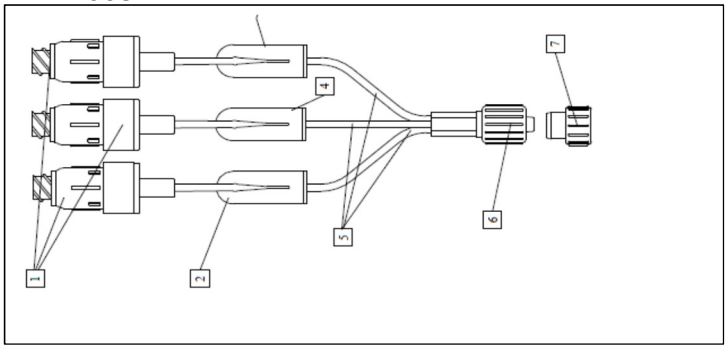
Example of product configuration product reference MFX2601MZ



MFX2602MZ



MFX2603MZ



BD MaxZero™ extension set with needle-free connector, Microbore, version January 2018

COMPONENT	**MATERIAL**
BD MaxZero™ EXTENSION SET W/NEEDLE-FREE CONNECTOR, MICROBORE	
MaxZero™ Needle-free connector, pocket version	PC, Silicone
Slide clamp, small, white	PP
Slide clamp, small, blue (models MFX2602MZ & MFX2603MZ)	PP
Slide clamp, small, red (model MFX2603MZ only)	PP
Tube 12 cm (1 mm x 2,1 mm)	PU
Protecting cap – for male luer lock	LDPE
Male luer lock (MFX2601MZ)	PC, ABS
2-way Male luer lock (MFX2602MZ)	PC, ABS
3-way Male luer lock (MFX2603MZ)	PC, ABS
PACKAGING	
Unitary Packaging	1 face paper, 1 face transparent
Box	carton

Tubing dimension and priming volume

PRODUCT REFERENCE	**PRIMING VOLUME (ML)**	**TUBE INNER DIAMETER (MM)**	**TUBE OUTER DIAMETER (MM)**
MFX2601MZ	0,4	1	2,1
MFX2602MZ	0,6	1	2,1
MFX2603MZ	0,9	1	2,1

1.4 Material of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

MATERIAL	COMMENT
Phthalates/DEHP	DEHP or other phthalates are not part of material formulation.
Latex	Natural rubber latex is not part of material formulation.
Bisphenol A	The polycarbonate used to manufacture the clear top and base of the MaxZero™ contains trace amounts of BPA.
Substances of animal origin BSE/TSE	The products in this technical data sheet are not made with substances of animal origin.
Polyvinyl chloride (PVC)	PVC is not part of material formulation.

1.5 REACH information

IMF maintains an active REACH compliance program and work closely with its supply base on an ongoing basis with a view to obtaining information on REACH Substances of Very High Concern ("SVHC") through regular communication and exchange.

1.6 Biocompatibility

IMF products comply with the requirements of the standard for biocompatibility of medical devices, ISO 10993 series Biological Evaluation of Medical Devices.

1.7 Sterilization

- ***Sterilization Method***: Ethylene Oxide Sterilization, standard that has been followed ISO 11135-1: 2007 ("*Sterilization for Healthcare products- Ethylene Oxide –Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices*). ETO residues are within applicable regulations.

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ETO Product Residue Test Results Summary - Example product

ETO RESIDUALS Extractions			Category Limit
Immediately after degassing	After 7 days	After 14 days	
Example set			
3,872 mg/device			4 mg / device
	1,696 mg / device		
		0,728 mg / device	

ECH RESIDUALS Extractions	Category Limit
After 7 days	
Example set	9 mg / device
0,080 mg / device	

Note:

Given example values are taken from tests on similar product to the products in this technical file (worst case scenario). More information related to specific product/batch is available on request.

1.8 Shelf life

Shelf life is 5 years for all product references in this technical data sheet.
Recommendations are to store in a clean and dry zone, shielded from the light, and to avoid extreme temperatures.

1.9 Standards

Regulations/ Standards	**Description**
EN ISO 9001: 2008	Quality Management System

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EN ISO 13485: 2012	Medical devices – Quality management systems – Particular Requirements for the application of EN ISO 9001
EN ISO 14971: 2013	Medical devices - Risk Management.
EN ISO 15223: 2013	Medical devices. Symbols to be used with medical devices labels, labelling and information to be supplied
EN 1041: 2013	Terminology, symbols and information provided with medical devices. Information supplied by the manufacturer with medical devices
EN ISO 10993-1: 2010	Biological evaluation of medical devices. Evaluation and Testing.
EN ISO 10993-4: 2009	Biological evaluation of medical devices. Selections of tests for interactions with blood.
EN ISO 10993-5: 2009	Biological evaluation of medical devices. Tests for in vitro cytotoxicity.
EN ISO 10993-10: 2014	Biological evaluation of medical devices. Tests for initiation and sensitization.
EN ISO 10993-11: 2009	Biological evaluation of medical devices. Tests for systemic toxicity.
EN ISO 11135: 2014	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1: 2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN 556-1: 2006	Sterilization of Medical Devices – Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilized medical devices
EN 868-1: 1997	Packaging materials and systems for medical devices which are to be sterilized. Part 1: General requirements and test methods
EN 868-2: 2009	Packaging for terminally sterilized medical devices. Part 2: Sterilization wrap. Requirements and test methods
EN ISO 11607-1: 2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2: 2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 1707: 1997	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Lock fittings
EN 20594-1: 1995	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Part 1: General Requirements

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EN ISO 8536-4: 2013	Infusion Equipment for medical use. Part 4: Infusion sets for single use, gravity feed.
EN ISO 8536-8: 2015	Infusion Equipment for medical use. Part 8: Infusion Sets for pressure apparatus.
EN ISO 8536-9: 2015	Infusion Equipment for medical use. Part 9: Infusion Sets for pressure equipment.
EN ISO 8536-10: 2015	Infusion Equipment for medical use. Part 10: Infusion Accessories.

Note:
Given standards are referring to the status at the moment of preparation of this document. More information or updates are available on request.

1.10 Classification

- **Class IIa** Medical Device under **Rule 2,** Annex IX of Medical Devices Directive93/42/EEC as amended.

1.11 GMDN code or UMDNS code

UMDNS: 16-649
TERM: Intravenous Administration Sets, General Purpose

1.12 Good Manufacturing practices

The entire manufacturing and testing processes are following the Good Manufacturing Practices as specified below

- Incoming raw materials are verified via material inspection and testing and our suppliers are approved via our vendor management system.
- In addition to the automatic on-line inspections, in-process inspections are performed in addition to final product testing to ensure compliance with approved specifications.
- The manufacturing and testing details of each batch of product are recorded on a batch record which is retained in accordance with our document control procedures
- IMF operates a system of internal and external audits to maintain compliance
- IMF confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.
- IMF reserves the right to use the internal change control procedure to change raw material suppliers and production process

1.13 Others

- Certificate of Food Contact (*COMMISSION REGULATION (EU) No. 10/2011 of January 14th, 2011 concerning materials and plastic objects intended to get in touch with foodstuffs)* is not required as IMF products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.
- Safety (Material) Data Sheets are not required for this product.

2. Packaging

2.1 Example Unit pack labeling

***Example product reference* MFX2601MZ**



UNIT CONTAINER LABELLING PRINTED WITH 16 LANGUAGES:
ENGLISH, FRENCH, SPANISH, ITALIAN, GERMAN, SWEDISH, DUTCH, NORWEGIAN, DANISH, FINNISH, HUNGARIAN, POLISH, SLOVENIAN, GREEK, CZECHISH, PORTUGUESE

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2.2 Example case labeling

***Example product reference* MFX2601MZ**



2.3 Shipper box label

Example product reference MFX2601MZ



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Version	Description of Change	Date	Signature	Company Stamp
01	Initial Release	06.03.2018		GIELSTER STÜCK 11 58513 LÜDENSCHEID TEL. 02351 5506-1 FAX 02351 5506-11 IMPROMEDIFORM GmbH