TECHNICAL DATA SHEET

Pressure Extension Lines, Serie DH

PHT, DEHP and natural rubber latex are not part of material formulation
Sterile, for Single Use

Products presented in this technical data sheet:
DH-10, DH-25, DH-40, DH-50, DH-80, DH-100, DH-150, DH-200

1. General Information

1.1 General

The products are disposable medical devices for the general purpose of supplying the circulatory system with fluids and are generally used when the required volume or duration of fluid administration make conventional injection methods (e.g., manual administration by clinician using a syringe) impractical and/or contraindicated.

The pressure extension lines include a length of flexible tubing, and Luer-Lock connectors that allow a user to connect the extension to the patient's intravascular access device on one side, and the other end of extension can be connected to IV Set. The intended use of pressure extension lines Serie DH is the use with pumps or syringe pumps.

The pressure extension lines comprised in this technical data sheet have the tubing with internal diameter of 2 mm and external diameter of 4,1 mm. They can withstand the pressure up to 20 bar.

PHT, DEHP and natural rubber LATEX are not part of material formulation.

PRODUCT REFERENCE	PRODUCT DESCRIPTION	TUBE LENGTH in cm	TOTAL LENGTH in cm	BOX (UNITS)
DH-10	Pressure Extension Line (20 bar) 2x4,1 mm – 10 cm	10	14	25/200
DH-25	Pressure Extension Line (20 bar) 2x4,1 mm – 25 cm	25	29	25/200
DH-40	Pressure Extension Line (20 bar) 2x4,1 mm – 40 cm	40	44	25/200
DH-50	Pressure Extension Line (20 bar) 2x4,1 mm – 50 cm	50	54	25/200
DH-80	Pressure Extension Line (20 bar) 2x4,1 mm – 80 cm	80	84	25/200
DH-100	Pressure Extension Line (20 bar) 2x4,1 mm – 100 cm	100	104	25/200
DH-150	Pressure Extension Line (20 bar) 2x4,1 mm – 150 cm	150	154	25/200
DH-200	Pressure Extension Line (20 bar) 2x4,1 mm – 200 cm	200	204	25/200

Further Features

PRODUCT REF.	GRAVITY USE	PUMP USE	VENTED SPIKE	BCV	ANTI-SYPHON VALVE	NFC	FILTER SIZE	CHANGE INTERVAL	LIPID RESIST.
DH-10	yes	Yes, up to 20 bar	no	no	no	no	no	Refer to hospital protocol	yes
DH-25	yes	Yes, up to 20 bar	no	no	no	no	no	Refer to hospital protocol	yes
DH-40	yes	Yes, up to 20 bar	no	no	no	no	no	Refer to hospital protocol	yes
DH-50	yes	Yes, up to 20 bar	no	no	no	no	no	Refer to hospital protocol	yes
DH-80	yes	Yes, up to 20 bar	no	no	no	no	no	Refer to hospital protocol	yes
DH-100	yes	Yes, up to 20 bar	no	no	no	no	no	Refer to hospital protocol	yes
DH-150	yes	Yes, up to 20 bar	no	no	no	no	no	Refer to hospital protocol	yes
DH-200	yes	Yes, up to 20 bar	no	no	no	no	no	Refer to hospital protocol	yes

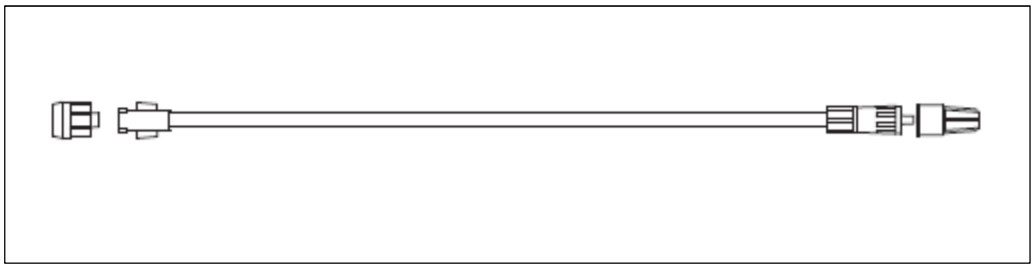
1.2 Certification

PRODUCT REF.	LEGAL MANUFACT.	MFG. SITE	ISO CERT. NO.	NOTIFY BODY	EC CERT. NO.	EU AUTHOR REP.	COUNTRY OF ORIGIN
DH-10 DH-25 DH-40 DH-50 DH-80 DH-100 DH-150 DH-200	Sendal S.L.U., Ctra. Nacional Madrid-Cáceres s/n, 10350 Almaraz, Spain	Sendal S.L.U., Ctra. Nacional Madrid-Cáceres s/n, 10350 Almaraz, Spain	ISO 13485:2012 + AC:2012 Q2N 16 11 64670 019	TÜV SÜD 0123	G2 17 09 64670 020	N/A	Spain

1.3 Material and product configuration

Example of product configuration, product reference

DH-10



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COMPONENT	**MATERIAL**
PRESSURE EXTENSION LINE, Serie DH	
Protecting Cap at Luer Lock female (white)	ABS
Luer Lock female	PVC (not made with DEHP)
Luer Lock male rotating	ABS+PP
Protecting Cap at Luer Lock male with membrane	PP+Versapor
Tube	PVC (not made with DEHP) - DOTP
PACKAGING	
Unitary Packaging	Polypropylene/Polyamide/Polyethylene 80 μm/Medical grade paper 60 g
Box	carton

Tube dimension and priming volume

PRODUCT REFERENCE	**PRIMING VOLUME (ML)**	**TUBE INNER DIAMETER (MM)**	**TUBE OUTER DIAMETER (MM)**
DH-10	0,41	2	4,1
DH-25	1,09	2	4,1
DH-40	N/A	2	4,1
DH-50	N/A	2	4,1
DH-80	1,91	2	4,1
DH-100	3,56	2	4,1
DH-150	5,21	2	4,1
DH-200	6,37	2	4,1

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 of the products presented in this technical data sheet.
Latex	Natural rubber latex is not part of material formulation of the products presented in this technical data sheet.
Bisphenol A	The products in this technical data sheet do not contain Bisphenol A.
Substances of animal origin BSE/TSE	The products in this technical data sheet are not made with substances of animal origin.
Polyvinyl chloride (PVC)	The products in this technical data sheet do contain PVC, moreover not made with added DEHP.

1.5 REACH information

SENDAL maintains an active REACH compliance program and works 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

SENDAL Medical products comply with the requirements of the standard for biocompatibility of medical devices, ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

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.

ETO Product Residue Test Results Summary - Example product

EO Results (1X) (<4mg/device)	ECH Results (1X) (<9mg/device)	Aeration	Quarantine	EO Results (2X) (<4mg/device)	ECH Results (2X) (<9mg/device)	Aeration	Quarantine
0,34	0,19	24h	24h	0,27	0,1	120h	24h

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 47 months for all product references in this technical data sheet.

Recommendations are to store in room temperature, in dry and warm place and not exposed to strong light.

1.9 Standards

STANDARDS	
ISO13485: 2012	Medical Devices – Quality Management System - Requirements for regulatory purposes
ISO 15223-1: 2012	Medical Devices - Symbols
ISO 8536-8: 2004	Infusion Sets for pressure apparatus.
ISO 8536-9: 2004	Infusion Sets for pressure equipment.
ISO 10993-1: 2009	Biological evaluation, links to parts 4,5,7,10,11
ISO 11135-1: 2007	EO Sterilization
ISO 11607-1: 2006	Packaging General Requirements
ISO 11607-2: 2006	Packaging Validation Requirements
EN-20594-1: 1994	Conical Fittings
ISO 14971: 2012	Risk Management

Note:

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

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1.10 Classification

Class IIa Medical Device under **Rule 2,** Annex IX of Medical Devices Directive 93/42/EEC as amended.

1.11 GMDN code or UMDNS code

GMDN code: 35833 (Electric infusion pump administration set/extension line, single-use)

Description: A collection of sterile devices (e.g., plastic tubing, check valve, roller clamp, Y-site connector, Luer, needle/catheter) intended to be used in combination with an electrically-powered infusion pump for the intravenous (IV), subcutaneous, intramuscular, or epidural administration of medication. This is a single-use device. See also: Infusion controller administration set; Ambulatory insulin infusion pump reservoir; Patient-controlled analgesia electric infusion pump administration set; Elastomeric infusion pump system; Mechanical infusion pump administration set

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
- Sendal operates a system of internal and external audits to maintain compliance
- Sendal confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.
- Sendal reserves the right to use the internal change control procedure to change raw material suppliers and production process

1.13 Other Information

- 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 BD 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.

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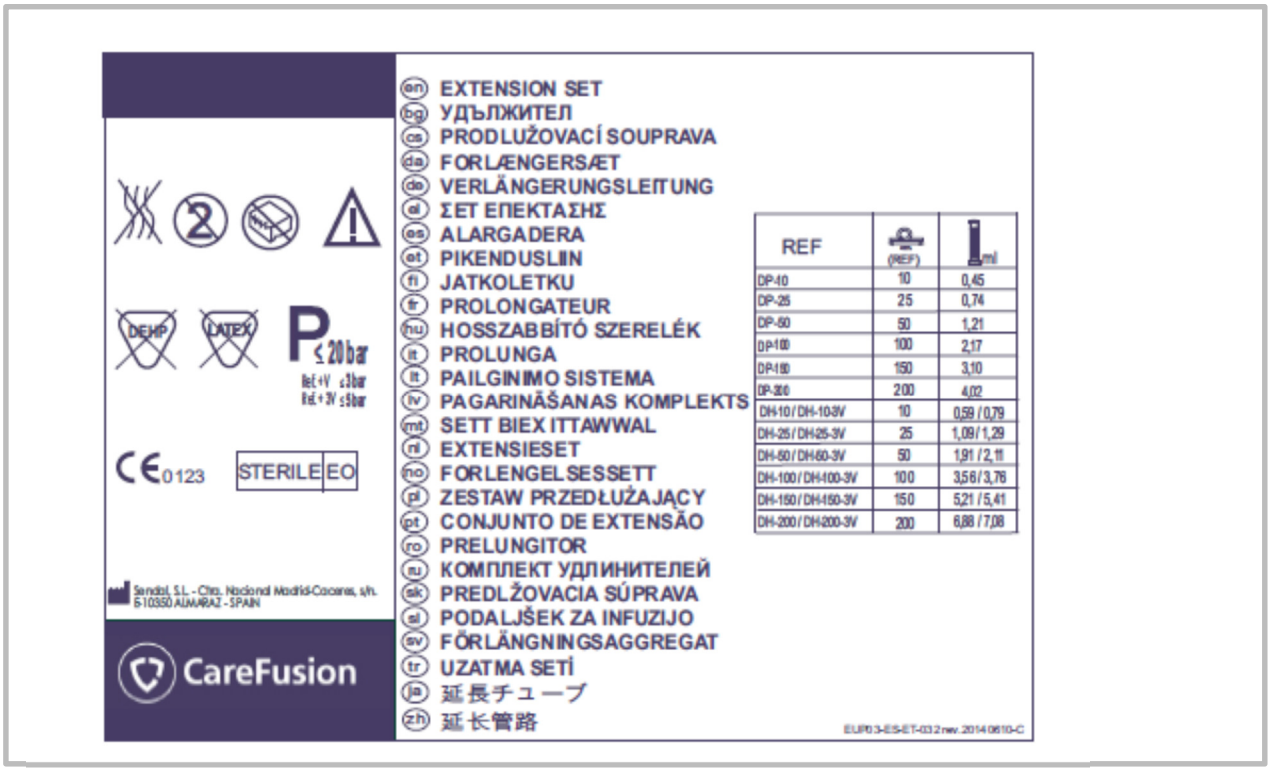
2. Packaging

2.1 Example Unit pack labeling

UNIT CONTAINER LABELLING PRINTED WITH 27 LANGUAGES

ENGLISH, BULGARIAN, CZECH, DANISH, GERMAN, GREEK, SPANISH, ESTONIAN, FINNISH, FRANCH, HUNGARIAN, ITALIAN, LATVIAN, LETONIAN, MALTESE, DUTCH, NORWEGIAN, POLISH, PORTUGUESE, ROMANIAN, RUSSIAN, SLOVAK, SLOVENIAN, SWEDISH, TURISH, JAPANESE, CHINESE

Example product reference DH-SERIE



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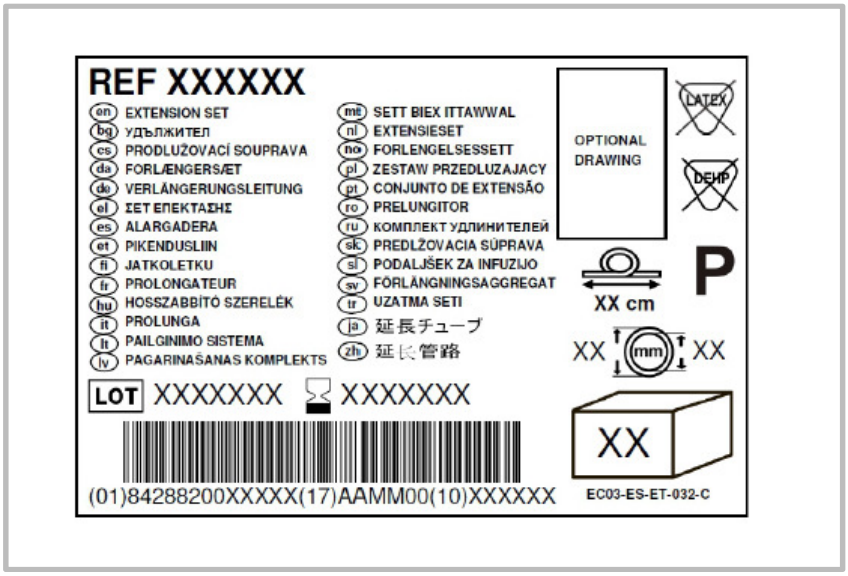
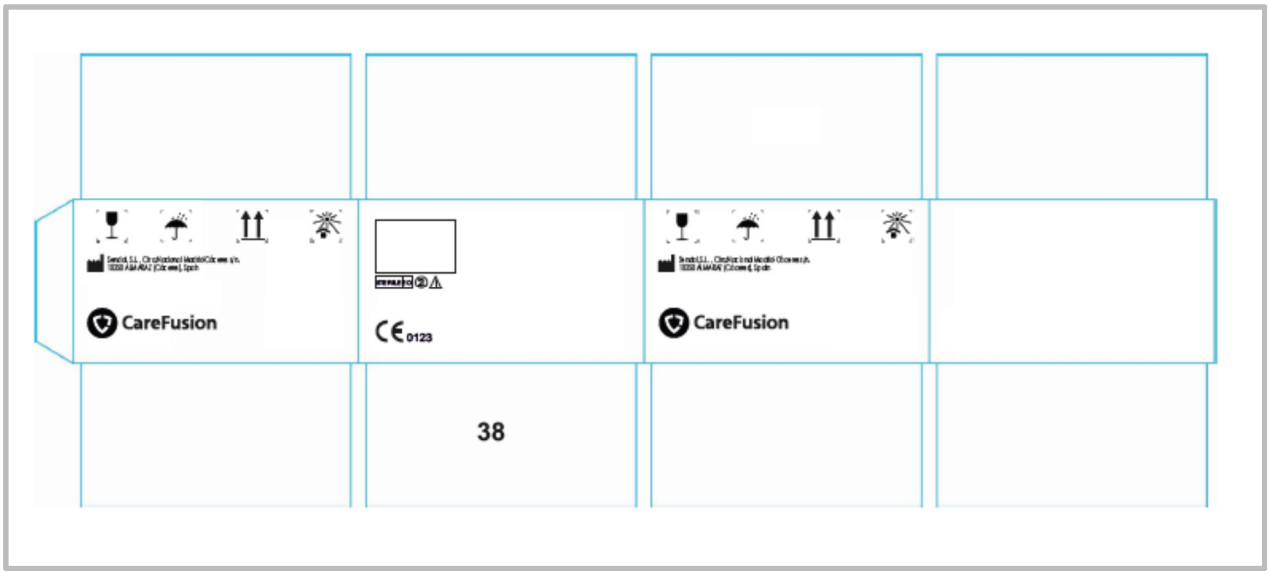
2.2 Shipper Label

Example product DH-SERIE



2.3 Box graphics



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Version	Description of Change	Date	Signature	Company Stamp
01	Initial Release	20-Mar-17		
02	Added product references: DH-25, DH-40, DH-50, DH-80, DH-100 and DH-150; Standard ISO 8536 changed, as only part 8 & 9 apply & standard ISO1135 taken away as does not apply; by Change Interval in **Further Features** table on page 3, now changed to: "Refer to hospital protocol" instead of "N/A" previously.	27-10-17		
03	Annual review 2018: 1.2.CE Certificate number updated 1.2.Tables visually improved 1.4.Wording with regard to materials of concern amended 1.5. REACH wording amended	9-Apr-18		

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	1.13 changed from "Others" to "Other Information"			