Document Number: EMEA-SOP039-F1	Rev. Lev.: 02
Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

Microbore extension Sets
Sterile, Single-use

Product codes: G40215H, G40615H, G40620H, 04105001509H, 04105003509H, 04105005509H, 04105007509H, 04105010509H, 04105025509H, 04105020508H, 04105030508H, 04105040508H

HANSCENT (NINGBO) CO., LTD
A305, NO.288 SANHENG ROAD,
CHANGHE INDUSTRIAL PARK,
CIXI, NINGBO, CHINA

TDS number: V201-249 Rev. 05
Veeva Vault number: BD-154396
2025-August

1. General Information

1.1 Intended purpose

The Microbore extension sets included in this document are specially designed as a tool for injection. Its basic use is for the intravascular administration of fluids.

1.2 Intended User

The Microbore extension sets included in this document are intended to be used by healthcare professionals who are experienced in IV infusion therapy.

1.3 General Medical Devices description

The Microbore extension sets consist of Luer Lock, PE (polyethylene) tube, and cap which is single use disposable, add-on device intended for the direct administration of fluids from a container into the patient's vascular system.
It is connected to primary IV sets to add length.
There are many types and specifications of Extension Tubes. The difference lies in the different pipe length, pipe color, assembly components, pipe winding and packing methods of extension pipe. Its products and components of material, structure production process are the same.



Figure 1: G40620H

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BD Catalogue Number	BD Product Description	Total Length (cm)	Tube Length (cm)	Priming Volume (mL)	Tube Diameter (mm)		Anti-Syphon Valve	Pump Use	Gravity Use
					Inner	Outer			
G40215H	Alaris™ Products. Microbore extension set, PE light protective, bore 1mm, 150cm	153	150	1.34	1	2	No	Yes	Yes
G40615H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 150cm	153	150	1.34	1	2	No	Yes	Yes
G40620H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 200cm	203	200	1.76	1	2	No	Yes	Yes
04105001509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 15cm	18	15	0.27	1	2	No	Yes	Yes
04105003509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 30cm	33	30	0.35	1	2	No	Yes	Yes
04105005509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 50cm	53	50	0.55	1	2	No	Yes	Yes
04105007509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 75cm	78	75	0.70	1	2	No	Yes	Yes
04105010509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 100cm	103	100	0.95	1	2	No	Yes	Yes
04105025509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 250cm	253	250	2.14	1	2	No	Yes	Yes
04105020508H	Alaris™ Products. Microbore extension set, PE, spiral bore 1mm, 200cm	203	200	1.70	1	2	No	Yes	Yes
04105030508H	Alaris™ Products. Microbore extension set, PE, spiral bore 1mm, 300cm	303	300	2.52	1	2	No	Yes	Yes
04105040508H	Alaris™ Products. Microbore extension set, PE, spiral bore 1mm, 400cm	403	400	3.36	1	2	No	Yes	Yes

Note: Please check BD catalogue number availability in your country.

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The BD Product Description can slightly differ from the Declaration of Conformity; please always refer to the BD Catalogue Number.

Other features:

BD Catalogue Number	Protecting Cap	Luer Lock	Vented Spike	Back Check Valve	Needle-Free Connector	Filter Size	Pressure Resistance	Change Interval	Lipid Resistance
G40215H	Yes	Rotating	No	No	No	N/A	Yes, up to 40 bar	According to Hospital protocol	Yes
G40615H	Yes	Rotating	No	No	No	N/A	Yes, up to 40 bar		Yes
G40620H	Yes	Rotating	No	No	No	N/A	Yes, up to 40 bar		Yes
04105001509H	Yes	Rotating	No	No	No	N/A	Yes, up to 40 bar		Yes
04105003509H	Yes	Rotating	No	No	No	N/A	Yes, up to 40 bar		Yes
04105005509H	Yes	Rotating	No	No	No	N/A	Yes, up to 40 bar		Yes
04105007509H	Yes	Rotating	No	No	No	N/A	Yes, up to 40 bar		Yes
04105010509H	Yes	Rotating	No	No	No	N/A	Yes, up to 40 bar		Yes
04105025509H	Yes	Rotating	No	No	No	N/A	Yes, up to 40 bar		Yes
04105020508H	Yes	Rotating	No	No	No	N/A	Yes, up to 2.5 bar		Yes
04105030508H	Yes	Rotating	No	No	No	N/A	Yes, up to 2.5 bar		Yes
04105040508H	Yes	Rotating	No	No	No	N/A	Yes, up to 2.5 bar		Yes

Light Protection: The following test has been carried out for G40215H

BD Catalogue Number	Test	Method	Specification	Wavelength
G40215H	Light Transmission Test	USP 671	T_{MAX} < 15%	≤ 450nm
			T_{MAX} < 20%	≤ 520nm

Where T_{MAX} is the maximum percentage of light transmitted through the product.

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1.4 Certification

BD Catalogue Number	Legal Manufacturer and ISO 13485 Certification	CE/UKCA Certificate Number and Notified Body Acronym and Number	Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative/ CH Representative (if applicable)
G40215H G40615H G40620H 04105001509H 04105003509H 04105005509H 04105007509H 04105010509H 04105025509H 04105020508H 04105030508H 04105040508H	Name and Address: Hanscent (Ningbo) Co., Ltd. A305, No.288 Sanheng Road, Changhe Industrial Park, Cixi, Ningbo, 315326 Zhejiang, P.R. China ISO 13485 Certificate No.: SX 2005588-1	CE certified with TÜV (0197) MDD Certificate No.: DD 2005588-1 UKCA certified: N/A	Name and Address: Hanscent (Ningbo) Co., Ltd. A305, No.288 Sanheng Road, Changhe Industrial Park, Cixi, Ningbo, 315326 Zhejiang, P.R. China ISO 13485 Certificate No.: SX 2005588-1	Name and Address: EC Representative: Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany Name and Address: CH Representative: CMC Medical Devices GmbH Bahnhofstrasse 32, CH-6300 Zug, Switzerland

1.5 UDI-DI and Basic UDI-DI

The products with the catalogue numbers referenced in this document are CE-certified under the Medical Device Directive (MDD). Hanscent (Ningbo) is transitioning to the Medical Device Regulation (MDR) and, as the information in this section is a MDR requirement, it is still not available. The Technical Data Sheet will be updated once the transition to MDR is completed.

1.6 Materials



Figure 2: Example drawing (G40615H, G40620H, G40215H, 04105001509H, 04105003509H, 04105005509H, 04105007509H, 04105010509H, 04105025509H)

BD Catalogue Number	Component	Material
G40615H G40620H G40215H 04105001509H 04105003509H 04105005509H 04105007509H 04105010509H 04105025509H	Tubing	Low Density Polyethylene (LDPE)
	Male Luer Lock	High Density Polyethylene (HDPE)
	Female Luer Lock	High Density Polyethylene (HDPE)
	Protecting Caps	Low / High Density Polyethylene (LDPE / HDPE)

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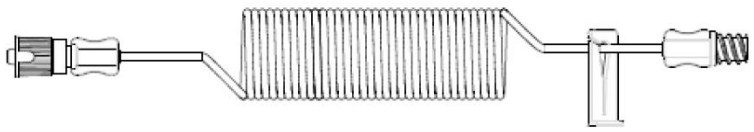

Figure 3: Example drawing (04105020508H, 04105030508H, 04105040508H)

BD Catalogue Number	Component	Material
04105020508H 04105030508H 04105040508H	Tubing	Low Density Polyethylene (LDPE)
	Rotating Luer Lock Collar	Medical grade ABS
	Rotating Luer Lock Core	High Density Polyethylene (HDPE)
	Female Luer Lock	High Density Polyethylene (HDPE)
	Protecting Caps	High Density Polyethylene (HDPE)
	Slide Clamp	Polypropylene (PP)

1.7 Materials 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 (Bis(2-ethylhexyl) phthalate) or other phthalates are not part of the material formulation.
Latex	Natural rubber latex is not part of the material formulation.
Bisphenol A	The products in this technical data sheet are not made with 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)	The products in this technical data sheet do not contain PVC.
PET/PETG – if relevant	The products in this technical data sheet is not made with PET/PETG

1.8 REACH information

Based on BD's ongoing data collection efforts and/or information received from BD's suppliers, BD has not identified any chemicals in the articles and packaging with the catalogue numbers referenced above , in an individual concentration above 0.1% weight by weight (w/w), which have been listed as SVHC and included in the "Candidate List" published by the European Chemical Agency (ECHA) on 25-Jun-2025 according to Art. 59 (1.10) of the Regulation (EC) N° 1907/2006 (REACH).

1.9 Biocompatibility

Hanscent (Ningbo) products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices.

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1.10 Sterilisation method

These products are sterilized using Ethylene Oxide.

1.11 Shelf life and storage conditions

The Microbore Extension Sets shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
Microbore Extension Sets have a shelf life of **3 years.**
Recommendations are to store in a clean and dry zone, shielded from the light, and to avoid extreme temperatures.

1.12 Applied Standards

As per the Technical Documentation:

Standard reference number	Title
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 15223:2023	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements
EN 15986:2011	Symbol for use in the labelling of medical devices. Requirements for labelling of medical devices containing phthalates
EN 1041:2008 + A1 2013	Information supplied by the manufacturer of medical devices
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing
ISO 10993-4:2017	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 10993-7:2008	Biological evaluation of medical devices. Ethylene oxide sterilization residuals
ISO 10993-10:2021	Biological evaluation of medical devices. Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices. Tests for systemic toxicity
EN ISO 11135:2014	Sterilization of health care products - Ethylene oxide: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1:2018	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
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
BS EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications. Connectors for intravascular or hypodermic applications.
ISO 8536-4:2019	Infusion equipment for medical use. Part 4: Infusion sets for single use, gravity feed
ISO 8536-8:2015	Infusion equipment for medical use. Part 8: Infusion sets for single use with pressure infusion apparatus
ISO 8536-9:2015	Infusion equipment for medical use. Part 9: Fluid lines for single use with infusion pressure equipment
ISO 14001:2015	Environmental Management System of the Manufacturing Site

Note:
The above standards reflect the status at time of document release.

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1.13 Classification

The Microbore Extension Sets are **Class Is** medical device according to Rule 2, Annex IX of Medical Devices Directive 93/42/EEC as amended.

1.14 Medical Device Nomenclature

GMDN Code: 12170
GMDN Term: Intravenous administration tubing extension set

EMDN code: A030201
EMDN Term: Extensions

1.15 Manufacturing practices

The entire manufacturing and testing processes are following the 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.
- Hanscent (Ningbo) operates a system of internal and external audits to maintain compliance.
- Hanscent (Ningbo) confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.

1.16 Other information

- Safety Data Sheets are not required for this product.
- Certificate of Food Contact (Commission Regulation EU 1183/2012 on "plastic materials and articles intended for contact with food" and Directive 2002/72/CE (as amended) "relating to plastic materials and articles intended to come into contact 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.
- Good Manufacturing Practices as defined by the EU Pharmaceutical is not applicable for Medical Devices.
- RoHS Directive: It is manufacturer' s view that the above-referenced products do not meet the definition of electrical and electronic equipment as stated in Art. 3(1) of Directive 2011/65/EU ("EU RoHS") and, therefore, do not fall within the scope of the EU RoHS Directive.

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2. Packaging

2.1 Packaging configuration

BD Catalogue Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
G40215H	Alaris™ Products. Microbore extension set, PE light protective, bore 1mm, 150cm	1	50	200	N/A
G40615H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 150cm	1	50	200	N/A
G40620H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 200cm	1	50	200	N/A
04105001509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 15cm	1	50	200	N/A
04105003509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 30cm	1	50	200	N/A
04105005509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 50cm	1	50	200	N/A
04105007509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 75cm	1	50	200	N/A
04105010509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 100cm	1	50	200	N/A
04105025509H	Alaris™ Products. Microbore extension set, PE, bore 1mm, 250cm	1	50	200	N/A
04105020508H	Alaris™ Products. Microbore extension set, PE, spiral bore 1mm, 200cm	1	50	200	N/A
04105030508H	Alaris™ Products. Microbore extension set, PE, spiral bore 1mm, 300cm	1	50	200	N/A
04105040508H	Alaris™ Products. Microbore extension set, PE, spiral bore 1mm, 400cm	1	50	200	N/A

*"No": IFU may be available but not as an insert.

2.2 Packaging materials

Component	Material
Unit Pack	1 face medical grade paper, 1 face transparent film
Shelf Box	PE Bag
Shipping Case	Carton

2.3 Recycled materials in packaging

-Recyclability of Packaging: Based on our ongoing data collection and/or information received from our suppliers, the secondary and tertiary portions of the packaging of the medical devices referenced above are recyclable (at least partially) according to EN 13430:2004. Some portions of the primary packaging may only be recyclable in the communities that have appropriate recycling facilities.

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2.4 Examples of labelling

Pouch label extracted from document G40215H Pouch Label - GIAC0353A REV 06 Revision 06 related to reference G40215H:



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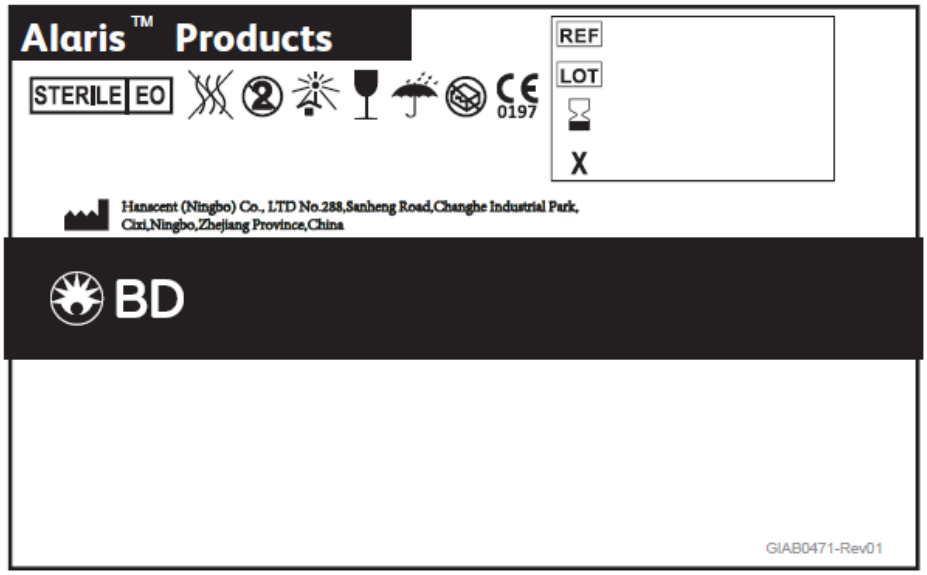
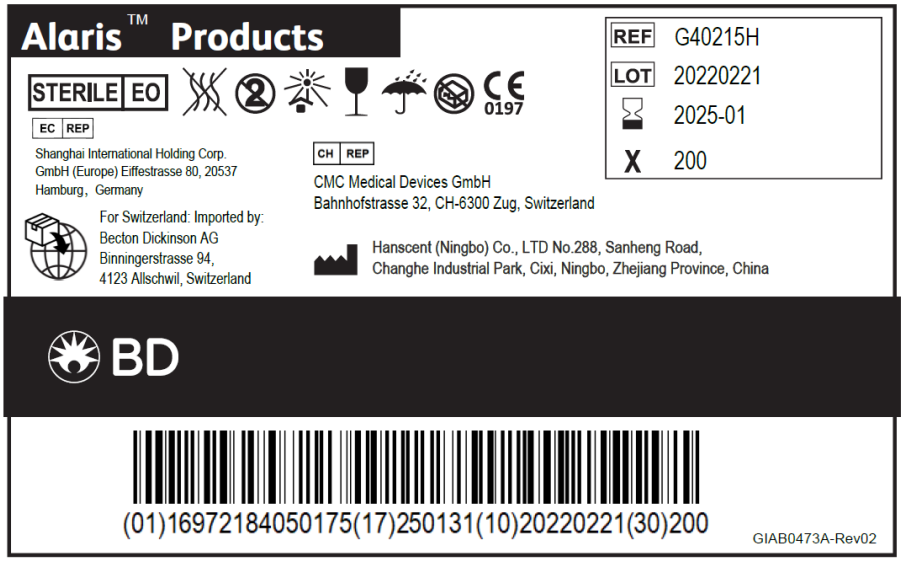
Shelf Box (Secondary Packaging) extracted from document GIAB0471 Revision 01 related to reference G40215H:



Shipper label extracted from document GIAB0473A - Rev02 Shipper Box Label revision 02 related to reference G40215H:



IFU insert is not applicable for the products included in this document.

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REVISION	CHANGE SUMMARY
01	Initial Release
02	Addition of spiral PE set SKUs, update priming volumes, primary packaging label and certificate numbers in S1.3
03	Addition of light protection test data to section 1.2
04	January 2022: - Correction of SKU in light protection test data in Section 1.2.
05	August 2025: - Updates according to TDS template EMEA-SOP039-F1 Rev.02 based on latest Technical Documentation validated by Hanscent (Ningbo) - Addition of TDS number and Veeva Vault number

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