BD Gravity Infusion Set, Micro, Series NT Sterile, for Single Use

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Product codes presented in this technical data sheet
NT-52-180ELLP, NT-52-LLRA

QS-TDS012 – Rev. 02
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1. General Information

1.1 Intended use

Gravity Infusion Sets are disposable medical devices for purpose of supplying the circulatory system with fluids. The general use is to provide patients body with infusion, in situations when the conventional injection methods (e.g., manual administration by clinician using a syringe) are impractical and/or contraindicated.

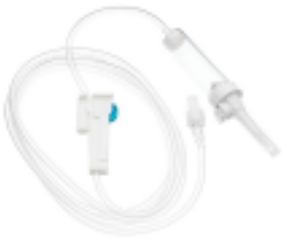
Gravity Infusion Set is a fluid administration set that has flexible tubing and on one side Luer Lock connector that allows a user to connect one end of the administration set to the patient's intravascular access device or extension set. The other end of the administration set has a drip chamber and sharp plastic spike for accessing a solution reservoir, such as an I.V. bag or bottle.

1.2 General description

Gravity Infusion Sets in this technical data sheet contain micro cannula, to be used in pediatrics. The following materials: DEHP, natural rubber latex are not part of the material formulation.
Drop size: 60 drops are equal 1g ± 0,1g (distilled water). IV Sets are pressure resistant up to 0,5 bar.

There are two types of the set in this technical data sheet, with regard to the distal end:

1. Standard set with luer lock and priming cap at the distal end, like the model NT-52-180ELLP and
2. Set with flash ball and the standard protecting cap at the distal end, like the model NT-52-LLRA



BD Catalog Number	BD Product Description	Tube Length (in cm)	Total Set Length (in cm)	Priming Volume (ml)	Tube Inner Diameter (cm)	Tube Outer Diamater (cm)
NT-52-180ELLP	Gravity Infusion Set Micro, vented/non-vented, 180 cm	180	188	13	3	4,1
NT-52-LLRA	Gravity Infusion Set Micro, vented/non-vented, with Flash Ball	200	208	15	3	4,1

Note: Please check BD catalog number availability in your country.
The BD Product Description can slightly differ from the Declaration of Conformity; please always refer to use the BD Catalog Number.

Further features:

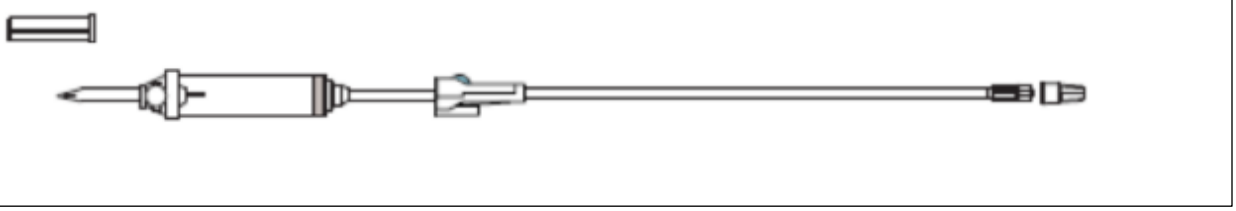
BD Catalog Number	Gravity Use	Pump Use	Ventilation Spike	Back Check Valve	Filter Size	Change Interval	Lipid Resistant
NT-52-180ELLP	Yes	No	Yes	No	15 mic. (Drip chamber filter)	According Hospital Protocol	Yes
NT-52-LLRA	Yes	No	Yes	No	15 mic. (Drip chamber filter)	According Hospital Protocol	Yes

1.3 Certification

BD Catalog Number	Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body Brief Name	Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
NT-52-180ELLP NT-52-LLRA	**Address:** Zibo Qiaosend Medical Articles Co., Ltd, No.2, Gaoyuan East Road, 256300 Gaoqing County, Shandong Province, People's Republic of China **ISO 13485** Certificate No.: Q5 088861 0011 Rev. 01	CE certified with TÜV SÜD **Certificate No.:** G2S 088861 0010 Rev. 03	**Address:** Zibo Qiaosend Medical Articles Co., Ltd, No.2, Gaoyuan East Road, 256300 Gaoqing County, Shandong Province, People's Republic of China **Country of Origin:** China **ISO 13485** Certificate No.: Q5 088861 0011 Rev. 01	MedNet EC-REP GmbH Borkstrasse 10, 48163 Muenster, Germany TEL : +49 251 32266-0 FAX : +49 251 32266-22

1.4 Materials

Example of product configuration, product reference NT-52-180ELLP



Component	Material
Drip Chamber	PVC (not made with DEHP, used plasticizer DINP)
Drip Chamber Filter 15 micron	Nylon + ABS
Spike	ABS
Air Vent by Spike	PVC
Protection Cap at Spike	PE
Flow Regulator and Wheel	ABS/ABS
Micro Cannula in the Drip Chamber	Stainless Steel
Tubing	PVC (not made with DEHP, used plasticizer DINP)
Male Luer Lock	ABS
Flash Ball at the Distal End (only model NT-52-LLRA)	Isoprene
Protecting Cap (model NT-52-LLRA)	PE
Priming Cap / Protecting Cap with Hydrophobic Membrane (hydrophobic membrane only by model NT-52-180ELLP)	PE / PTFE

1.5 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	Phthalates/DEHP are not part of materials formulation.
Latex	Natural rubber latex is not part of material formulation.
Bisphenol A	The products are not made with Bisphenol A.
Substances of animal origin BSE/TSE	The raw materials used in the manufacture of this device are not made with rests of animal tissue / derivate.
Polyvinyl chloride (PVC)	These products contain polyvinyl chloride, however not with added DEHP.
PET/PETG – if relevant	PET/PETG are not part of materials formulation.

1.6 REACH information

REACH (Regulation (EC) No 1907/2006) is a European Regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals. Zibo Qiaosend Medical Articles Co., Ltd. maintains an active REACH compliance program and pro-actively communicates with its upstream suppliers to obtain information on REACH Substances of Very High Concern (SVHC).

1.7 Biocompatibility

Zibo Qiaosend Medical Articles Co., Ltd. Medical products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices.

1.8 Sterilization method

Sterilization Method: Ethylene Oxide Sterilization, standard that has been followed ISO 11135: 2014 (*"Sterilization for Healthcare products- Ethylene Oxide: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices*). ETO residues are within applicable regulations.

Residue values: 0,68mg after 24h, 0,65mg after 48h, 0,59mg after 72h, 0,54mg after 96h, 0,51mg after 120h, 0,43mg after 144h, 0,35mg after 168h aeration.
The values we give are from sterilization validation files and are measured on example product. And we put the note below that the values are only example values.

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

1.9 Shelf life and storage conditions

The Gravity Infusion Set from Series NT shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.

Gravity Infusion Set, references NT-52-180ELLP and NT-52-LLRA have a shelf life of 48 months.

Zibo Qiaosend Medical Articles Co., Ltd recommend to store in a dry and warm place, not exposed to strong light nor extreme temperature.

1.10 Standards

As per extract from the Declaration of Conformity:

Standards	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 15223: 2016	Medical devices. Symbols to be used with medical devices labels, labelling and information to be supplied
EN ISO 8536-4: 2010 (AMD1 2013)	Infusion Equipment for medical use. Part 4: Infusion sets for single use, gravity feed.
EN 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/AC2009	Biological evaluation of medical devices. Ethylene oxide sterilization residuals.
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11: 2018	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 11607-1: 2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2: 2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 14971: 2019	Packaging for terminally sterilized medical devices - Validation requirements for forming, sealing and assembly processes

Note: The above standards reflect the status at the time of drafting this document. More information or updates are available on request in the Declaration of Conformity.

1.11 Classification

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

1.12 UMDNS code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), Gravity Infusion Sets in this technical data sheet, references NT-52-180ELLP and NT-52-LLRA are referenced as follows:
UMDNS Code: 12157
UMDNS Term: Intravenous Administration Sets

1.13 Manufacturing practices

Zibo Qiaosend Medical Articles Co., Ltd. is following the *Medical Equipment Production & Quality Management Standard* issued by the SFDA (equivalent to GMP)

We also follow the below-listed procedures:

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

1.14 Other information

- (Material) 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 ZIBO QIAOSEND 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 FDA Pharmaceutical is not applicable for Medical Devices.

2. Packaging

2.1 Packaging configuration

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
NT-52-180ELLP	Gravity Infusion Set Micro, vented/non-vented, 180 cm	1	N/A	200	No
NT-52-LLRA	Gravity Infusion Set Micro, vented/non-vented, with Flash Ball	1	N/A	200	No

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

2.2 Packaging material

Component	Material
Unit Pack	Medical grade paper 60g +PE film 50g
Shelf Box	Carton
Shipping Case	Carton
IFU	N/A

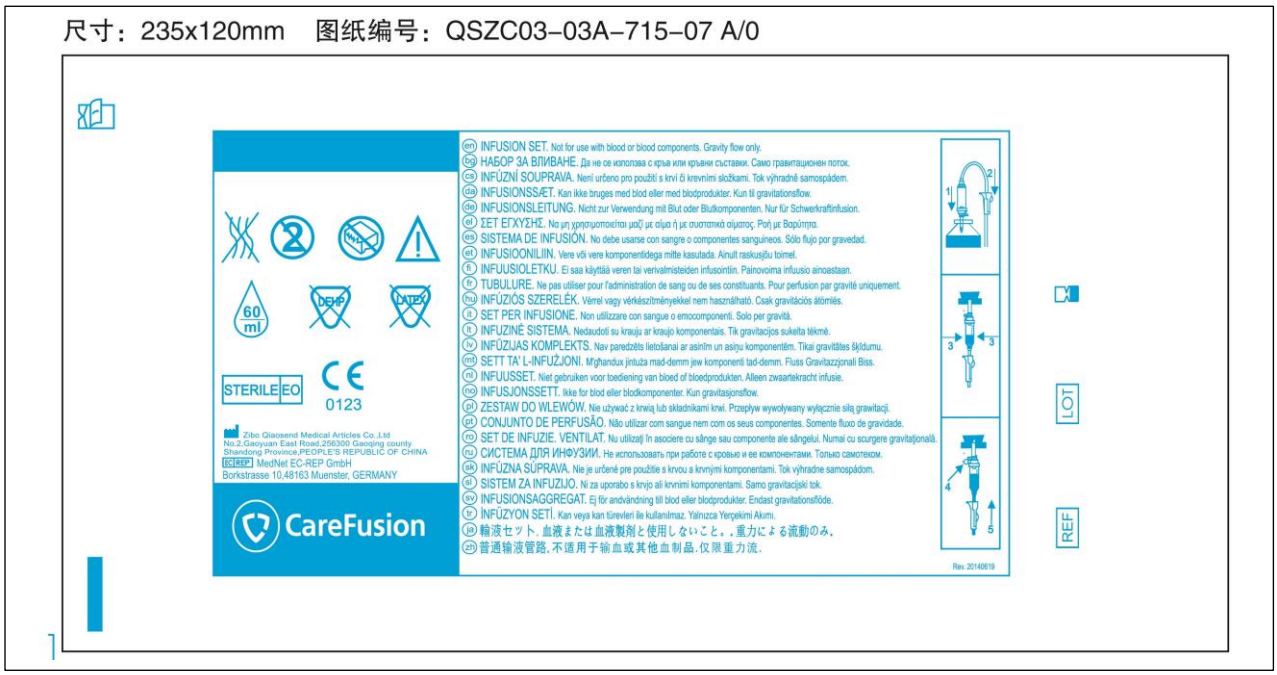
2.3 Examples of labeling

Labels: According to European Medical Device directive, labels are multilingual.

UNIT CONTAINER LABELLING PRINTED WITH 27 LANGUAGES:

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

Primary Packaging Label (Top Web) received from Zibo Qiaosend related to all references of Range NT:



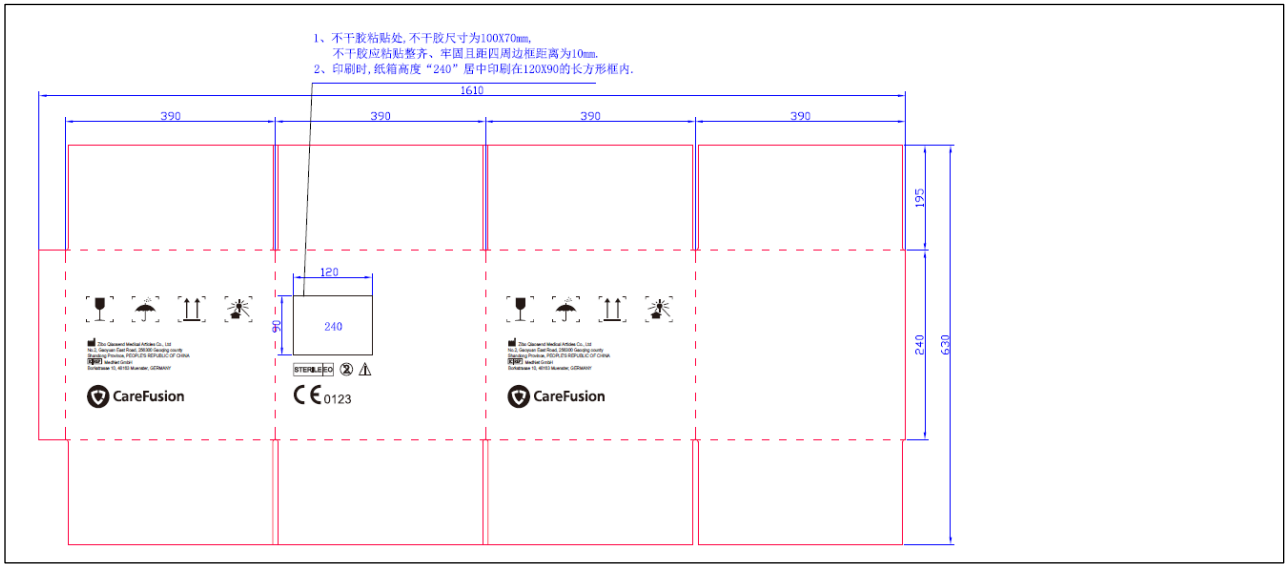
Shelf Box:

N/A

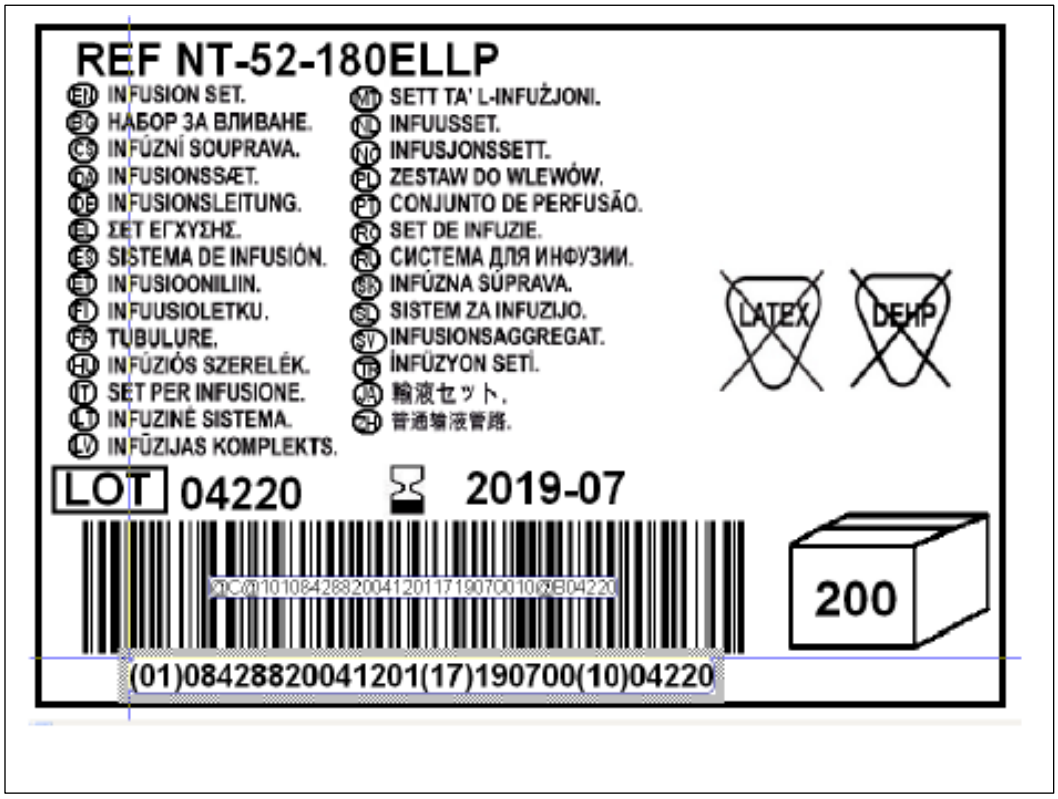
Shelf Box label:

N/A

Shipping Case received from Zibo Qiaosend related to all references of Range NT:



Case Label received from Zibo Qiaosend related to reference NT-52-180ELLP:



IFU insert (English part only):

N/A

REVISION	CHANGE SUMMARY
01	Initial release according to new template, CO # 20448
02	New TDS template revision-Rev.02-applied; Annual review 2020, CO#20969

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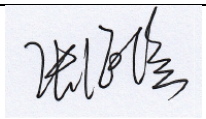
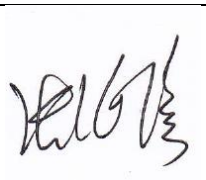
Version	Description of Change	Date	Signature	Company Stamp
01	Initial Release	MAR.25, 2017		
02	Review 2019: New BD template applied; Section 1.3. Certifications: CE Certificate number and ISO Certificate number updated; EC Representative name and address updated; Section 1.5. Materials of concern: added material: PET/PETG – if relevant; Sections 1.6., 1.7., 1.9., 1.12. Text slightly changed-according the new template; Section 1.8. Sterilization method: ISO 11135: 2007 updated to ISO 11135: 2014; Section 1.10. Standards: List of standards updated according the new Declaration of Conformity Section 2. Packaging: added tables 2.1. Packaging configuration and 2.2. Packaging material	MAY.28, 2019		

Space reserved for 3rd party Signature and Stamp (Zibo Qiaosend)				
03	Review 2020: New version, version 02 of the BD technical data sheet template applied; Section 1.3. Certifications: ISO Certificate revision number updated to Rev.01; CE Certificate updated to Rev.03; Changed name of the EC-Representative from *MedNet GmbH* to *MedNet EC-REP GmbH* Section 1.4. Materials: added used plasticizer Section 1.9. Shelf life and storage conditions: statement wording changed, included Zibo Qiaosend recommendation Section 1.10. Standards – standards versions updated Section 1.14. Other information: statement wording changed, including *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" and comment to Good Manufacturing Practices* Section 2.3. – changed example of unitary label – as EC-REP name slightly changed (see section 1.3. changes); Language order changed: languages listed in alphabetical order	Jun.11, 2020	张海滨