Naman Inc., Ahmedabad, Gujarat (India).

Technical File

Document No.	**NI/TECH/01**
Revision	02
Date	25–04–2024

Whichever directives is applicable mention here

Applicable Directives (Please select applicable directive considering your product)	**93/42/EEC**	**Medical device – general**
	2006/42/EC	**Machinery Directive**
	2014/35/EU	**Low voltage Directive**
	2014/30/EU	**EMC Directive**
	2016/425	**Personal Protective Equipment Regulation**
	305/2011	**Construction Product Regulation**
	2014/68/EU	**Pressure Equipment Directive**
	1907/2006	**REACH – Regulation**
	2011/65/EU	**RoHS – Restriction of Hazardous Substance – Directive**
	2012/19/EU	**Waste electrical and electronic equipment Directive**
	2014/34/EU	**ATEX Directive**
	2009/48/EU	**Toy Directive**
	2014/53/EU	**Radio Equipment Directive**
	2013/53/EU	**Recreational Craft Directive**
	90/385/EEC	**Active Implant Medical Devices Directive**
	93/15/EEC	**Explosive for civil use Directive**
	2000/14/EC	**Noise Emission in the Environment Directive**
	2009/142/EC	**Gas Appliances Directive**
	2014/33/EU	**Lifts Directive**
	2007/23/EC	**Pyrotechnic Directives**

Prepared By		Approved By	
Technical Head		**Chairman**	
Designation	Signature	Designation	Signature

1.0 Index

Sr. No.	Document Name	Doc. No. NI/TECH/01/	Total pages	Revision number and date 0	1	2	3
1.	Index	01	1 – 2	25-04-2024			
2.	Scope of Products under CE Certifications	02	1	25-04-2024			
3.	Company Profile	03	1	25-04-2024			
4.	Quality Control and Manufacturing Facilities	04	1 – 3	25-04-2024			
5.	Manufacturing Flow chart	05	1	25-04-2024			
6.	Product Descriptions – Technical Specification	06	1	25-04-2024			
7.	Bill of materials	07	1	25-04-2024			
8.	Product Drawings	08	1	25-04-2024			
9.	Product Test Reports	09	1 – 2	25-04-2024			
10.	Product Validation Records	10	1	25-04-2024			
11.	Procedure for controlled environment conduct (with contamination control	11	1	25-04-2024			
12.	Procedure for facility maintenance	12	1	25-04-2024			
13.	Procedure for equipment operations and maintenance	13	1	25-04-2024			
14.	Procedure for batch records	14	1	25-04-2024			
15.	Procedure for Identification and Traceability	15	1 – 2	25-04-2024			
16.	Process for Handling, storages Packaging, Preservation and Delivery	16	1 – 2	25-04-2024			
17.	Procedure for final product release	17	1	25-04-2024			
18.	Procedure for receiving inspection	18	1	25-04-2024			
19.	Process for deviation	19	1	25-04-2024			
20.	Procedure for retain samples	20	1	25-04-2024			
21.	Procedure for stability studies	21	1	25-04-2024			
22.	Process for product recall	22	1	25-04-2024			
23.	Procedure for post market surveillance	23	1 – 2	25-04-2024			
24.	Process for Validation	24	1 – 2	25-04-2024			

Prepared By		Approved By	
Technical Head		**Chairman**	
Designation	Signature	Designation	Signature

6.0	Product description

Naman Inc.

In pursuit of meeting customer requirements it has always been **"Naman"** constant endeavor since inception to bring out new products that will help to Doctors and patient during hospitalization. The broad specifications of the products are listed below ;

Sr. No.	Model	Description of products	Specifications (Overall approx. size)
Main Products – Non active medical devices			
1.	NI–01	Infusion set with built in airvent	
2.	NI–02	Infusion sets with / without Airway	
3.	NI–03	Micro Drip Set	
4.	NI–04	Blood Administration set	
5.	NI–05	Blood administration set with molded chambers	
6.	NI–06	Urine bag	
7.	NI–07	URO Store	
8.	NI–08	URO Store	
9.	NI–09	Scalp vain set pouch pack / blister pack	
10.	NI–10	Measure volume set	

45.0 List of harmonized standards

Sr. No.	Name of harmonized standard	Edition / Revision	Year of Publication
1.	Symbol to be used with medical device labels, labeling and information to be supplied – BS EN ISO 15223–1	====	2016
2.	Small bore connectors for liquid and gases in Healthcare applications – connectors for intravascular or Hypodermic Applications – IS/ISO 80369–7	====	2016
3.	Sterilization of Healthcare products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical device – BS EN ISO 11135:2014+A1	2014	2019
4.	International standard (ISO 2859:1)	2nd edition	1999
5.	Medical devices – quality management systems – requirements for regulatory purpose. ISO: 13485	3rd edition	2016
6.	Sterilization of medical devices – requirements for medical devices to be designated “sterile” BS: EN 556–1:2001	====	2001
7.	Quality management – guidelines for training – IS/ISO 10015:1999	RA 2015	1999
8.	Quality systems medical devices – particular requirements for the application of en: iso-9002	1st edition	2016
9.	Quality systems – medical devices – particular requirements for the application of EN: ISO 9001	5th edition	2015
10.	Biological evaluation of medical devices IS:12572 (part – 1) 1994 ISO: 10993-1	5th edition	2018
11.	BS EN ISO 14971	====	2019
12.	Biological evaluation of medical devices IS: 12572 (part – 2) ISO: 10993-2	2nd edition	2006
13.	Biological evaluation of medical devices IS: 12572 (part – 14) ISO: 10993-4	3rd edition	2017

46.0 Essential safety requirements

Sr. No.	Process	Essential Safety Requirement
1.	Receiving raw material (for chemical composition)	Checking the receipt of the raw material
		Receiving the T.C. from the supplier
2.	Receiving raw material – needle (for damaged parts)	Checking the receipt of the raw material
		Receiving the T.C. from the supplier
3.	Receiving raw material (for biological)	To monitor microbial count regularly
4.	Clean room	Monitoring controlled environment area
5.	Assembly (for leak test)	Implement assembly check points
6.	Sterilization (for residual E.O.%)	Validated sterilization process
7.	Packaging – Damage during transit	Validated packaging
		Collect T.C. from the supplier.
8.	Labeling – wrong labeling	Provide advisory notice

27.0 Procedure for risk analysis

1.0	**Purpose**
	The purpose of the procedure is to establish a system of risk analysis
2.0	**Scope**
	This procedure is applicable to Production and Quality Control (Inspection) activities carried–out at Naman Inc.
3.0	**Responsibility**
	• **Head of Production and Quality Control** are overall responsible for implementation of this procedure and ensuring proper receiving inspection of all materials.
4.0	**Forms / Records / Reference**
	• EN 4441 • Procedure for Failure, Mode, Effect, Analysis
5.0	**Description of Activity**
1.	S1–General: Risk Analysis is carried out as a part of quality management system using FMEA as a tool; the Results of Risk analysis is documented.
2.	S2–Identifications of qualitative and quantitative characteristics: Identified all characteristics affecting to product safety with their defined limits.
3.	S3–Identifications of Possible hazards: Identified possible hazards associated with device in both normal and fault condition.
4.	S4–Estimation of the Risks for each hazard: Estimated the risk of identified hazards.
5.	S5–Acceptability of Risk: appropriate measures for risk acceptance levels are considered as per limit specified in Harmonized standards.
6.	S6–Risk reduction: Estimated risks are reduced appropriately by implementing corrective & preventive actions.
7.	S7–Generation of other hazards: No other new hazards were determined during risk reduction procedure.
8.	S8–Adequacy of device safety: All the identified hazards are at an acceptable level. The product / device is found safe for the intended application and use.
6.0	**Reporting**
	• Top Management
7.0	**Reference documents**
	1. Risk analysis work sheet

Prepared By		Approved By	
Technical Head		**Chairman**	
Designation	Signature	Designation	Signature

26.0 Procedure for CE Marking

1.0 Purpose

The purpose of this procedure is to establish and maintain a system for CE Marking on products.

2.0 Scope

This procedure is applicable to CE certified products manufactured at Naman Inc.

3.0 Responsibility

Technical Heads and Head of Production is responsible to implement and to monitor the CE Marking activities within the Organization

4.0 Forms / Records / Reference

- Nil

5.0 Description Of Activity

5.1 CE Marking

- The CE marking of conformity must appear in a visible, legible and identifiable form on the products and on the instruction for use, on the sales brochures.
- It is prohibited to affix marks, which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking. Any other mark may be affixed to the device, to the packaging or to the instruction accompanying the device provided that the visibility and legibility of the CE marking is not thereby reduced.

The CE conformity marking shall consist of the initials **"CE"**

- If the marking is reduced or enlarged the proportions given in the above drawing must be respected.
- The various components of the CE marking must have substantially the same. Vertical dimensions, which may not be less than 5 mm.

5.2 Wrongly Affixed CE Marking

- Where a member state establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the community shall be obliged to end the infringement under conditions imposed by the member state.
- Where non–compliance continues, the member state must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market.

6.0 Reporting

- Top Management

7.0 Reference documents

Prepared By		Approved By	
Technical Head		**Chairman**	
Designation	Signature	Designation	Signature

44.0 Declaration of conformity

Put declaration of conformity as below in your company letter pad (Scan and put in this page)

DECLARATION OF CONFORMITY

Group – A (Comes in direct contact with the body)

Sr. No.	Devices	Referred Harmonized Standard
1	Infusion Set	BS EN ISO 15223–1, IS/ISO 80369–7, BS EN ISO 11135:2014+A1, ISO 2859
2	Blood Administration Set	BS EN ISO 15223–1, IS/ISO 80369–7, BS EN ISO 11135:2014+A1, ISO 2859
3	Blood Donor Set	BS EN ISO 15223–1, IS/ISO 80369–7, BS EN ISO 11135:2014+A1
4	Measured Volume Set	BS EN ISO 15223–1, IS/ISO 80369–7, BS EN ISO 11135:2014+A1
5	Scalp Vein Set	BS EN ISO 15223–1, IS/ISO 80369–7, BS EN ISO 11135:2014+A1
6	Urethal	BS EN ISO 15223–1, IS/ISO 80369–7, BS EN ISO 11135:2014+A1
7	Foleys Catheter	BS EN ISO 15223–1, IS/ISO 80369–7, BS EN ISO 11135:2014+A1
8	Male External Catheter	BS EN ISO 15223–1, IS/ISO 80369–7, BS EN ISO 11135:2014+A1
9	Chest Drainage Catheter	BS EN ISO 15223–1, IS/ISO 80369–7, BS EN ISO 11135:2014+A1
10	Abdominal Drainage Kit	BS EN ISO 15223–1, IS/ISO 80369–7, BS EN ISO 11135:2014+A1

I hereby declare that,

1. Infusion set & Blood Administration set manufactured at Naman Inc, Ahmedabad is in conformity with the provisions of the 93/42/EEC Directives. (Mention here the applicable directive)
2. All the relevant information on the products is covered in 'Technical file'.
3. No application has been lodged with any other notified body for "CE Marking".
4. The company is also ISO 9001:2015 Certified firm.
5. Any malfunction or deterioration and/or performance of a device, as well as inadequacy in the labeling or the instruction for use which might lead to or might have led to the death of a patient or user to a serious deterioration in his state of health will be immediately intimated to notified body.
6. Any technical or medical reason connected with the characteristics or the performance of a device leading to a systematic recall of devices will be immediately intimated to notified body.
7. The specified product is meeting the sterilization conditions as described in technical file and we will maintain it.
8. We agree to abide by all rules and regulations laid down in the directive.

Prepared By		Approved By	
Technical Head		**Chairman**	
Designation	Signature	Designation	Signature

EU Declaration of Conformity

CE

Manufacturer

Naman Inc.

Trade Mark

Naman Brand

Product

PVC Channel (Cable Trunking System)

Type

R–II and R–III

The EU Directives covered by this Declaration

2014/35/EU Low Voltage Equipment Directive and reference standard BS EN 50085, Part–1

Sr. No.	Reference standard	Ref. Compliance report
1.	BS EN 50085, Part–1	CIPET, CA (Ref. Test Report No. 4564, Dt. 01–06–2020) and CIPET, LA (Ref. Test Report Sl. No. 12108, Dt. 28–05–2020)
	73/23/EEC (2006/95/EC)	

The Basis on which Conformity is being declared

The product identified above complies with the requirements of the above EU Directives by meeting the BS EN 50085, Part–1 – Cable Trunking and cable ducting system for electrical installations– General requirements. The technical documentation required to demonstrate that the product meets the requirements of the Low Voltage Directive has been complied by the signatory below and is available for inspection by the relevant enforcement authorities. The CE mark was first applied on 2011.

The products described above comply with the essential requirements of the directives specified.

ATTENTION!

The attention of the specifier, purchaser, installer, or user is drawn to special measures and limitations to use which must be observed when the product is taken into service to maintain compliance with the above directives. Details of these special measures and limitations to use are available on request, and are also contained in the product catalogue.

Signed on → 25st April 2024

Sr. No.	Requirements	Compliance
CHAPTER – I	**Scope, placing on the market and freedom of movement**	
Article 1		
1.	This Directive applies to machinery and lays down the essential health and safety requirements there for, as defined in Annex I.	
1.1	It shall also apply to safety components placed on the market separately	
2.0	For the purposes of this Directive	
	Machinery means • An assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material, • Interchangeable equipment modifying the function of a machine, which is placed on the market for the purpose of being assembled with a machine or a series of different machines or with a tractor by the operator himself in so far as this equipment is not a spare part or a tool;	
	Safety components means • A component, provided that it is not interchangeable equipment, which the manufacturer or his authorised representative established in the Community places on the market to fulfill a safety function when in use and the failure or malfunctioning of which endangers the safety or health of exposed persons.	
3.0	Where, for machinery or safety components, the risks referred to in this Directive are wholly or partly covered by specific Community Directives, this Directive shall not apply, or shall cease to apply, in the case of such machinery or safety components and of such risks on the implementation of these specific Directives.	
4.0	Where, for machinery, the risks are mainly of electrical origin, such machinery shall be covered exclusively by Directive 73/23/EEC (8).	
Article 2		
1.0	Member States shall take all appropriate measures to ensure that machinery or safety components covered by this Directive may be placed on the market and put into service only if they do not endanger the health or safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for their intended purpose.	
2.0	This Directive shall not affect Member States' entitlement to lay down, in due observance of the Treaty, such requirements as they may deem necessary to ensure that persons and in particular workers are protected when using the machinery or safety components in question, provided that this does not mean that the machinery or safety components are modified in a way not specified in the Directive.	
3.0	At trade fairs, exhibitions, demonstrations, etc., Member States shall not prevent the showing of machinery or safety components which do not conform to the provisions of this Directive, provided that a visible sign clearly indicates that such machinery or safety components do not conform and that they are not for sale until they have been brought into conformity by the manufacturer or his authorised representative established in the Community. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons	
Article 3		
1.0	Machinery and safety components covered by this Directive shall satisfy the essential health and safety requirements set out in Annex I.	
Article 4		
1.0	Member States shall not prohibit, restrict or impede the placing on the market and putting into service in their territory of machinery and safety components which comply with this Directive.	