1. **Intended Purpose:** This document describes the product design and technical requirements of the Dialyzer. As per Council Directive 93/42/EEC of 14th June 1993 as amended by 2007/47/EC concerning medical devices Dialyzer is classified as class IIb and this product shall comply with essential requirements of Medical Devices Directive 93/42/EEC as amended by 2007/47/EC and product standard.

2. **Intended Use of device:** Dialyzer has been designed for use in the extracorporeal hemodialysis and associates forms of treatment of chronic renal failure or acute kidney failure. Dialysis filter is a disposable medical device used for patients suffering from reduced or absent chronic renal function. It is an artificial kidney, used to filter fluids and wastes from a dialysis patient's blood.

3. **Product Description & Features:** Dialyzer works on the principle of diffusion of solutes and ultrafiltration of fluid across a semi-permeable membrane Diffusion is a property of substances in water, substances in water tend to move from an area of high concentration to an area of low concentration. Blood flows by one side of a semi-permeable membrane, and a dialysate fluid flows by the opposite side. A semipermeable membrane is a thin layer of material that contains holes of various sizes, or pores. Smaller solutes and fluid pass through the membrane, but the membrane blocks the passage for larger substances (for example, red blood cells, large proteins).

   This replicates the filtering process that takes place in the kidneys, when the blood enters the kidneys and the larger substances are separated from the smaller ones in the glomerulus. State-of-the-art housing and membrane technology.

   3.1 Types of Dialyzer: There are two types of Dialyzer

      1. High Flux
      2. Low Flux

   3.2 The term 'flux' refers to the permeability of the membrane in the dialyzer (artificial kidney) across which accumulated toxins and excess fluid pass during Haemodialysis.

   3.3 The 'low-flux' cellulosic dialyzers could easily remove the smaller toxins such as urea and creatinine, but larger molecules that are normally removed by normal kidneys were unable to fit through the pores.

   3.4 A 'high-flux' dialyzer has a membrane that allows middle-sized molecules to pass through but prevents the accidental removal of protein from the blood.

   3.5 **Dialyzer is available in sizes** - 1.1 m^2, 1.3 m^2, 1.4 m^2, 1.5 m^2, 1.6 m^2 & 1.7 m^2.

   3.6 Product classification as per EN ISO 10993-1:2009 / ISO 10993-1:2018

      3.6.1 **Device Connected with**: Blood Line Set, Dialysis Machine.
      3.6.2 **Contact Duration:** *B*-Prolonged Exposure
      3.6.3 **Categorization of Device** - External Communicating Device.
      3.6.4 **Area of Contact:** Circulating Blood
      3.6.5 **Applicable Biocompatibility Tests:** Cytotoxicity, Sensitization, Irritation, Acute-Systemic Toxicity, Sub-acute Toxicity, Genotoxicity, Implantation, Hemocompatibility.

4. REFERENCE DOCUMENTS

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager – QA		21.02.2020
Checked By	RD Sharma	DGM – QA & RA		21.02.2020
Approved By	SS Rawat	Head – QA		21.02.2020

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Date: 2021.04.16 20:45:14 EEST
Reason: MoldSign Signature
Location: Moldova

S. No.	Document Code	Document Description
Harmonized standards		
4.1	EN ISO 13485:2016	Quality system - Medical Devices - Requirements for the Regulatory Purposes
4.2	93/42/EEC	European council directive as amended by 2007/47/EC
4.3	EN ISO 14971:2012	Application of risk management to medical devices
4.4	EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
4.5	EN ISO 11137-2:2015	Sterilization of health care products, Radiation, Establishing the sterilization dose
4.6	EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems
4.7	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied- Part 1: General requirements
4.8	EN 1041:2008	Terminology, Symbols and information provided with Medical Devices; Information supplied by the manufacturer with medical devices
4.9	EN 62366:2008	Medical Devices – Application of usability engineering to medical devices
4.10	EN ISO 10993 -1:2009 / AC:2010	Biological evaluation of medical devices – Evaluation and testing within a risk management process.
4.11	EN ISO 10993-3:2014	Biological evaluation of medical devices – Tests for genotoxicity, carcinogenicity and reproductive toxicity.
4.12	EN ISO 10993-4:2009	Biological evaluation of medical devices – Selection of tests for interaction with blood
4.13	EN ISO 10993-5:2009	Biological evaluation of medical devices – Tests for in vitro cytotoxicity
4.14	EN ISO 10993-6:2009	Biological evaluation of medical devices – Tests for local effects after implantation
4.15	EN ISO 10993-11:2009	Biological evaluation of medical devices – Tests for systemic toxicity
4.16	EN ISO 10993-12:2012	Biological evaluation of medical devices – Sample preparation and reference materials
4.17	EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products.
4.18	EN ISO 11737-2:2009	Sterilization of medical devices — Microbiological methods —Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
Non-Harmonized Standards		
4.19	ISO 8637-1:2017	Extracorporeal systems for blood purification - Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators
4.20	ISO 8637-2:2018	Extracorporeal systems for blood purification -- Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and hemofilters.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		21.02.2020
Checked By	RD Sharma	DGM – QA & RA		21.02.2020
Approved By	SS Rawat	Head – QA		21.02.2020

S. No.	Document Code	Document Description
4.21	ISO 14644-1:2015	Cleanroom and associated controlled environments - Classification of air cleanliness
4.22	ISO 10993-10:2010	Biological evaluation of medical devices – Tests for irritation and delayed-type hypersensitivity
4.23	USP / IP	United States Pharmacopoeia / Indian Pharmacopoeia
4.24	ISO 11737-1:2018	Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.
Internal Standard/Documents		
4.25	QP/QPL/5.01	Quality Planning
4.26	QP/DLZ/5.01	Manufacturing of Dialyzer
4.27	QP/ECD/01	EC Vigilance
4.28	FP/QA/5.145	In Process specification of Dialyzer
4.29	FP/QA/5.144	Finished product specification of Dialyzer
4.30	WI/DLZ/5.11	Procedure for Final Inspection of Dialyzer
4.31	WI/DLZ/5.13	Pouch and Box Packing of Dialyzer
4.32	PM/QA/5.01	Film for Blister Packing/ Pouch Packing
4.33	PM/QA/5.02	Specification for paper for packing
4.34	PM/QA/5.04	Specification for corrugated box
4.35	PM/QA/5.06	Specification for labels
4.36	RM/QA/5.09	Plastic Raw Material Testing
4.37	WI/IVC/5.02	Maintenance of Clean Room
4.38	GTP/QC/5.14	Monitoring of Bio-burden of clean room manufacturing area
4.39	GTP/QC/5.09	Sterility Test
4.40	GTP/QC/5.10	BET Test
4.41	TF/RA/84	Risk analysis of product
4.42	Drg. Assy. 90365-90368	Flux Dialyzer
4.43		

5. Shelf Life

The products shall conform to the specifications and functional requirements for a maximum of Three years from the date of manufacturing.

6. Sterilization:

6.1 Dialyzer shall be sterilized with Gamma Radiation as per standardized and validated sterilization cycle as per EN ISO 11137-1:2015 and EN ISO 11137-2:2015 by M/s. Shriram Institute for Industrial Research. The detailed record of routine monitoring is maintained with the QA as well as production department. Product is exposed to minimum 25 kilo grays (kGy) of Gamma radiation.

6.2 Dialyzer is irradiated to achieve sterility. During the re-sterilization cycle this negative pressure may be disrupted and therefore the Dialyzer may not achieve its intended purpose.

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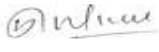
Prepared By	Anila Raj K N	Asstt. Manager - QA		21.02.2020
Checked By	RD Sharma	DGM – QA & RA		21.02.2020
Approved By	SS Rawat	Head – QA		21.02.2020

6.3 Product appearance and functional performance is not compromised by sterilization cycles as the product is sterilized and the package of product remained intact.

7. MATERIAL

All component materials should be such that components and product assemblies will pass material testing as specified in specifications.

S. No.	Parts Where Material is used	Base Material	Grade	CAS No.
1	Housing	Poly Carbonate	MAKROLON 2458 550115	25037-45-0
		PP	Bormed HD850MO	9003-07-0
			Bormed RF830MO-12	
			PurellRP375R	
2	Blood Port cap	Poly Carbonate	MAKROLON 2458 550115	25037-45-0
		PP	Bormed HD850MO	9003-07-0
			Bormed RF830MO-12	
			PurellRP375R	
3	Potting Ring	Poly Propylene	H110MA	9003-07-0
4	Potting cap	Poly Propylene	H110MA	9003-07-0
5	Twist Lock Cap	HDPE	HI 1600	25087-34-7
6	Dialysate Cap	LLDPE	M24200	9002-88-4
7	O Ring	Silicon	VMQ40	68083-18-1
8	Fibers Bundle	Poly Sulfon	NA	28212-68-2, 25135-51-7
9	Potting reservoir	Poly Propylene	H110MA	9003-07-0
10	Unit package Paper	Medical Grade Paper	N/A	N/A
11	Unit Package Transparent Film	PP + PA Film	N/A	N/A
12	Shipper Box (Big /Small)	Corrugated Paperboard	N/A	N/A

8. COMPONENT AND PROCEDURE FOR ASSEMBLY

8.1 Components for Dialyzer

Sr. No.	Component	Process
1	Housing	Injection Molding
2	Blood Port cap	Injection Molding
3	Potting Ring	Injection Molding
4	Potting cap	Injection Molding
5	Twist Lock Cap	Injection Molding
6	Dialysate Cap	Injection Molding
7	O Ring	Injection Molding
8	Potting reservoir	Injection Molding

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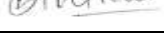
Prepared By	Anila Raj K N	Asstt. Manager - QA		21.02.2020
Checked By	RD Sharma	DGM – QA & RA		21.02.2020
Approved By	SS Rawat	Head – QA		21.02.2020

8.2 Assembly

- **Laser fiber Sealing:** The potting ring Assembly, fiber insertion, fiber sealing and potting cap fixing is done as per Work Instruction No WI/DLZ/5.04.
- **Potting:** The potting gluing & curing is done as per Work Instruction No. WI/DLZ/5.05.
- **Cutting:** The Potting Cap removing & cutting is done as per Work Instruction No. WI/DLZ/5.06.
- **Screwing:** The blood port cap screwing is done as per Work Instruction No. WI/DLZ/5.07.
- **Wetting & testing:** The wetting & testing is done as per Work Instruction No. WI/DLZ/5.08.
- **Drying:** The drying is done as per Work Instruction No WI/DLZ/5.09.
- **Final Inspection:** After drying operation, product is sent for final inspection & fitment of twist cap (red & blue) & dialysate cap as per WI/DLZ/5.11

8.3 Assembled Dialyzer

a. All ends of the Product must be free from leakage at ultra-filtration Pressure (300mmHG).

b. At ultra-filtration flow rate of 3000ml/hr transmembrane pressure should increases to a value greater than 300 mmHg.

c. The connector should be properly locked with housing port.

d. Urea Reduction Ratio (URR) and Kt/V (pronounced "kaytee over vee") are two tests that tell if you are getting enough dialysis.

e. URR of Dialyzer should be at least 65 percent or your Kt/V should be at least 1.2.

f. Always check the appearance of your dialyzer before treatment.

9. FUNCTIONAL SPECIFICATIONS

9.1 Dialyzer Housing: It is a 1.1 m^2, 1.3 m^2, 1.4 m^2, 1.5 m^2, 1.6 m^2 & 1.7 m^2 surface area dialyzer housing. Across this housing all the functioning of dialysis takes place. It is a body of Dialyzer that contains semipermeable filter (polysulphone).

9.2 Blood Pot Cap: It is used to regulate the passage of Blood during dialysis attached adjacent to the housing.

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Checked By	RD Sharma	DGM – QA & RA		21.02.2020
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9.3 Potting Ring: It is a ring attached adjacent to the housing for potting compound filling purpose.

9.4 Potting Cap: Cap attached to potting ring adjacent side of dialyzer housing for covering purpose during potting compound is filled.

9.5 Potting Reservoir: It is attached to the dialyzer separately for filling up the potting compound for filter sealing purpose.

9.6 Twist Lock Cap: This cap is screwed with the port of Blood port cap as where blood enters and exit across housing during Dialysis. It also use for covering of port to protect from contamination .

9.7 Dialysate Cap: It is used on housing port where dialysate enters and exit during operation. Its purpose is only for covering of port to protect from contamination.

9.8 O- Ring: It is connected to blood port cap that provide sealing purpose during dialysis. Its material is silicon used for sealing purpose.

9.9 Polysulphone Filter: It is a low flux filter used for main blood filtration purpose through semipermeable membrane.

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Prepared By	Anila Raj K N	Asstt. Manager - QA		21.02.2020
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9.10 Packaging

9.10.1 Unit package shall be a clear Polypropylene (70%) + Polyamide (30%) film.

9.10.2 Unit package shall maintain a sterility barrier through its seal. The integrity of the package shall not be compromised during normal handling, storage, sterilization or transportation.

9.10.3 Unit package shall open reliably without tearing and particulate matter generation.

9.10.4 Twenty-eight (28) pcs of unit packages shall be packed into one corrugated shipper box, as per customer requirement.

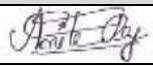
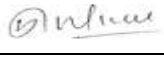
9.10.5 The combination of shipper box/unit packaging system shall provide adequate product protection during normal shipping, handling and storage, till the product reaches the end user.

10 ENVIRONMENT FOR COMPONENT MOLDING

- The product is molded in controlled area by injection molding. The controlled area is frequently monitored for environmental temperature and humidity by using calibrated thermo hygrometer.
- The product is manufactured in clean room-controlled conditions. The clean room is class-7 (in Static condition) meeting requirements set by ISO 14644-1:2015 for Clean Room. Clean rooms are provided with high efficiency particulate air filter (HEPA) and controlled temperature and humidity. The area is maintained as per WI/IVC/74.
- The clean rooms are frequently monitored for environmental bio burden by using settling plate method. The bio burden method, frequency and limit of colony forming unit (CFU) are defined in GTP/QC/5.14.

11 CLASSIFICATION

- As per "Classification Criteria" in Annexure - IX of the Council Directive 93/42/EEC as amended by 2007/47/EC "Dialyzer" is used for more than 60 minutes and less than 30 days. Hence used for 'short-term use' as per description in the 1.1 of Annexure - IX.
- The device "Dialyzer" does not penetrate body orifice & does not go beyond pharynx and nasal cavity hence this device is "Non –invasive device" as per 1.2 of Annexure IX. The product Dialyzer is intended for modifying the chemical composition of blood by removing the excess wastes and fluid from the blood (undesirable toxic substances).
- As per Rule 3 for Classification of Annexure IX of directive 93/42/EEC as amended by 2007/47/EC all 'Non-invasive devices' intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class llb medical devices. Hence, the product Dialyzer is classified as Class IIb Medical Device.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		21.02.2020
Checked By	RD Sharma	DGM – QA & RA		21.02.2020
Approved By	SS Rawat	Head – QA		21.02.2020

12 QUALITY PLAN

- A three tier Quality Plan is followed consisting of the Quality System Manual, the Standard Operating Procedures (SOPs) and Work Instructions and Formats.
- These take care of all the functional responsibilities of the management and company employees, production and quality control at various stages. It also takes care of the Quality Assurance needs and compliance with the various national and international standards and regulations. Quality planning is done as per QP/QPL/5.01.
- The Quality Plan covers all incoming, in-process and finished products. The control and process are defined in the SOPs and Work Instructions and the observations are recorded in Formats and Registers.

REVISION SUMMARY

Supersedes	***Effective Date***	***Reason for Review/Revision***
Nil	-	New Issue

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		21.02.2020
Checked By	RD Sharma	DGM – QA & RA		21.02.2020
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