1. PURPOSE

This document describes the product design and technical requirements of the medical disposable product. As per Council Directive 93/42/EEC of 14th June 1993 as amended by 2007/47/EC concerning medical devices Extension Lines are classified as class IIa device and these products shall comply with essential requirements of Medical Devices Directive 93/42/EEC as amended by 2007/47/EC and the product standards, ISO 8536-9:2015.

2. INTENDED USE OF PRODUCTS

Extension lines are used to connect the infusion site and the source of infusion (i.e. to connect the IV Cannula or Three Way Stop Cock and IV Set) to extend the path between infusion site & source of infusion with 6% luer connection to minimize mechanical irritation and infection.

3. PRODUCT DESCRIPTION AND FEATURES

The product is available in PE & PVC material with high pressure & low-pressure capacity in sizes- 10 cm, 20cm, 25 cm, 30 cm, 35 cm, 50 cm, 60 cm, 85cm, 90 cm, 100 cm, 150 cm, 120cm, 150 cm, 200 cm, 250 cm, 300cm & 400cm. Available with Male luer at one end and female luer at other ends. The product is sterilized using EO (Ethylene Oxide) gas. The product and/or product packaging doesn't contain any constituents of any animal origin.

3.1 Low Pressure Extension Line

3.1.1 Extension line suitable for low pressure applications.
3.1.2 Kink resistant frosted PVC tubing.
3.1.3 For pressure up to 4.5 bars (65 psi).
3.1.4 Available with or without clamp.
3.1.5 Also available with injection Y-site (latex or latex free) for intermittent medication.
3.1.6 Tube Diameter (I Ø X O Ø): 3.0 mm X 4.1 mm & 2.5 mm x 4.1 mm.
3.1.7 Available with and without DEHP plasticizers.
3.1.8 Male Luer lock at one end & female Luer lock at another end.

3.2 High Pressure Extension Line

3.2.1 Small-bore high-pressure extension line suitable for high pressure monitoring.
3.2.2 Kink resistant PVC tubing resistant to breakage and damage.
3.2.3 For pressures up to 55 bars (800 psi).
3.2.4 Residual volume: 1.0 ml per 100 cm.
3.2.5 Tube Diameter (I Ø X O Ø): 1.0 mm X 2.0 mm, 1.0 mm X 3.0 mm & 1.5 mm X 3.0 mm.
3.2.6 Male Luer lock at one end & female Luer lock at another end

3.3 PVC Free High-Pressure Extension Line (Straight & Coiled)

3.3.1 Kink resistant PE / PP tubing.
3.3.2 Tube Diameter (I Ø X O Ø):1.0 mm X 2.0 mm & 1.5 mm X 3.0 mm.
3.3.3 Residual volume: 1.70 ml per 100 cm.
3.3.4 Sterile, Non-pyrogenic and Non-toxic fluid path.
3.3.5 For pressure up to 55 bars (800 psi).
3.3.6 Male Luer lock at one end & female Luer lock at another end

Digitally signed by Chirtoacă Iurie
Date: 2021.03.14 19:40:35 MSK
Reason: MoldSign Signature
Location: Moldova

3.4 T type Extension Line

3.4.1 Small-bore high-pressure extension line suitable for high pressure monitoring with a T-type Female luer.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head - QA		01.04.2020

3.4.2 Available in 15 cm tube length.

3.5 Product classification as per EN ISO 10993-1:2009 / Ac:2010

3.5.1 **Device Connected with** – Infusion set, IV Cannula, Three way Stop cock.

3.5.2 **Categorization of Device** – External Communicating Device.

3.5.3 **Area of Contact** – Blood path Indirect

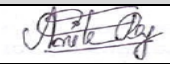
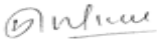
3.5.4 **Contact Duration** – B-Prolonged

3.5.5 **Applicable Biocompatibility Tests** - Cytotoxicity, Sensitization, Irritation, Acute-Systemic Toxicity, Haemocompatibility.

4. REFERENCE DOCUMENTS

S. No.	Document Code	Document Description
Harmonized standards		
4.1	EN ISO 13485:2016	Medical devices - Quality management systems - 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 10993-1:2009 / AC:2010	Biological evaluation of Medical Devices Part-1 Evaluation & testing within a risk management process.
4.5	EN ISO 10993-4:2009	Biological evaluation of medical devices – Selection of tests for interaction with blood
4.6	EN ISO 10993-5:2009	Biological evaluation of medical devices – Tests for in vitro Cytotoxicity
4.7	EN ISO 10993-7:2008 / AC:2009	Biological evaluation of Medical Devices Part-7 Ethylene oxide sterilization Residuals
4.8	EN ISO 10993-11:2018	Biological evaluation of medical devices – Tests for systemic toxicity
4.9	EN ISO 10993-12:2012	Biological evaluation of medical devices – Sample preparation and reference materials
4.10	EN ISO 11737-1:2006 / AC:2009	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganism on products
4.11	EN ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation & maintenance of a sterilization process
4.12	EN ISO 11135-1:2007	Sterilization of health care products – Ethylene Oxide Part – 1: Requirements for development, validation & routine control of a sterilization process for medical device
4.13	EN ISO 15223-1:2016	Symbols to be used with medical devices labels, labeling and information to be supplies
4.14	EN 15986:2011	Symbols to be used with medical devices labels, labeling and information to be supplies
4.15	EN 20594-1:1993/ A1:1997	Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - Part 1: General Requirements
4.16	EN 1707:1996	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain

S. No.	Document Code	Document Description
		other medical equipment. Lock fittings
4.17	EN ISO 11607 -1:2009	Packaging for terminally sterilized medical devices – requirements for materials, sterile barrier & packaging systems.
4.18	EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices – Validation requirements for forming, sealing and assembly process.
4.19	EN 1041:2008	Terminology, Symbols and information provided with Medical Devices; Information supplied by the manufacturer with medical devices
4.20	EN 62366:2008	Medical Devices – Application of usability engineering to medical devices
Non-Harmonized Standards		
4.21	ISO 9001:2015	Quality management system - Requirements
4.22	ISO 8536-9:2015	Infusion Equipment for medical use - Fluid lines for use with pressure infusion equipment.
4.23	ISO 8536-10:2015	Infusion Equipment for medical use- Accessories for fluid lines for use with pressure infusion equipment.
4.24	ISO 11135:2014	Validation and routine control of EO Sterilization
4.25	ISO 11737-1:2018	Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
4.26	EN 868-5:2018	Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods.
4.27	ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
4.28	ISO 10993-10:2010	Biological evaluation of medical devices – Tests for irritation and delayed-type hypersensitivity
4.29	ISO 14644-1:2015	Clean rooms and associated controlled environments – Classification of air cleanliness
4.30	USP / IP	United States Pharmacopoeia / Indian Pharmacopoeia
Internal Standards / Documents		
4.31	QP/ECD/01	EC Vigilance
4.32	QP/QPL/01	Quality Planning
4.33	FP/QA/09	Specifications of Extension Line
4.34	FP/QA/24	Process Control of Extension Line
4.35	WI/MDS/04	Assembly of Extension Line
4.36	RM/QA/09	Plastic Raw Material
4.37	PM/QA/01	Specification for film for blister and pouch packing
4.38	PM/QA/02	Specification for paper for packing
4.39	PM/QA/03	Specification for duplex box
4.40	PM/QA/04	Specification for corrugated box
4.41	PM/QA/06	Specification for labels

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head - QA		01.04.2020

S. No.	Document Code	Document Description
4.42	PM/QA/15	Specification for paper pouch
4.43	PM/QA/28	PP Bag for IV set, Connection Tube, Extension Tube, BT Set, Urine Bag, Levin's Tube & Flow Regulator
4.44	GTP/QC/09	Sterility Test
4.45	GTP/QC/10	BET Test
4.46	TF/RA/03	Risk Analysis of product
4.47	Drg. No. Assly- 1012L	Assembly Drawing for Extension Tube (Low pressure)
4.48	Drg. No. Assly- 1012H	Assembly Drawing for Extension Tube (High pressure)
4.49	Drg. No. Assly- 1032	Assembly Drawing for PVC Free Extension Tube (Straight)
4.50	Drg. No. Assly- 1033	Assembly Drawing for PVC Free Extension Tube (Coiled)

5. SHELF LIFE

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

6. STERILIZATION

6.1 **Paper and plastic film pouches/Soft Blister packed product**: Product is sterilized with Ethylene Oxide (EO) gas as per standardized and validated sterilization cycle as per EN ISO 11135-1:2007/ ISO 11135:2014. The packaging of the device is made of polypropylene & polyethylene film and medical grade paper. The medical grade paper is designed to allow maximum exchange of ethylene oxide, air and moisture. For detailed validation repo refer to QA department. Based on validation result the routine cycle for sterilization is summarized as follows:

S. No.	Particular	*Limit*
1	**Preconditioning** (i) Time (ii) Temperature of chamber (iii) Humidity	 60 minute ± 2 minutes 45°C (±5°C) 30% ~ 90%
2.	**Conditioning** (i) Vacuum drawn and rate (ii) Vacuum holding time (iii) Temperature of chamber (iv) Humidity of chamber	 -0.75Kg/cm2@30min.±15min. 10 minute ± 1 minutes 45°C (±5°C) 30% ~ 90%
3	**Sterilization** (i) EO gas inlet temperature (ii) Concentration of EO gas (iii) Temperature of chamber (iv) Exposure time	 Not less than 20°C 550 mg/lit. ± 25 mg/lit. 45°C (±5°C) 280 minutes*±1min.*
4.	**Aeration** (i) Vacuum drawn and rate (ii) Total number of aerations	 *-0.75kg/cm2@ 40min ± 20 min.* 2 nos.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head - QA		01.04.2020

The detailed record of routine monitoring is maintained with the QA as well as production department.

6.2 Product appearance and functional performance is not compromised by up to three EO sterilization cycles as the product is sterilized three times and the package of product remained intact. The ethylene oxide residue was also found within limit.

6.3 Revalidation is done once in a year. The calibration of instruments like pressure gauge, temperature gauge, temperature indicator and controller, PT 100 etc. are done time to time as per their due date of calibration.

7. MATERIAL

7.1 All component materials selected comply with the specification. The product and packaging do not contain any constituents of animal origin.

S. No.	Part where material is used	Base Material	Grade	*CAS Number*
1	PVC Tubing (Low pressure)	Poly Vinyl Chloride	IP 31 / BT 31	9002-86-2
2	PVC Free Tubing (High pressure)	LDPE	24FS040	9002-88-4
3	PVC Tubing (High pressure)	Poly Vinyl Chloride	BT 9 / IP 85	9002-86-2
4	DEHP Free Tubing	Poly Vinyl Chloride	IP 31ND / BT 31ND	9002-86-2
5	Luer Lock	HDPE	50 MA 180	9002-88-4
6	Male / Female Luer (PE)	HDPE	M 200056	9002-88-4
7	Male Luer (PVC)	Rigid PVC	MMP 20B	9002-86-2
8	MLL cap	HDPE	M200056	9002-88-4
9	Screw cap	Poly Carbonate	1201-15	25037-45-0
10	Protector	Poly Propylene	SM 498 / 575 P	9003-07-0
11	Unit package Paper	Medical Grade Paper	OCPSxxxx10x	N/A
12	Unit Package Film	PP+PE Film	Medical grade / Non-toxic	N/A
13	Duplex Box	Semi craft paper	N/A	N/A
14	Transit Package	Cardboard boxes	N/A	N/A
15	EO Gas	30% EO & 70% CO2	N/A	N/A

8. COMPONENT AND PROCEDURE FOR ASSEMBLY

8.1 Extension Lines

8.1.1 Components

(i) Male Luer Connector - Injection molding
(ii) Female Luer Connector - Injection molding
(iii) Luer Lock - Injection molding
(iv) Tubing - Extrusion

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head - QA		01.04.2020

(v) Screw Cap - Injection molding
(vi) Protector - Injection molding

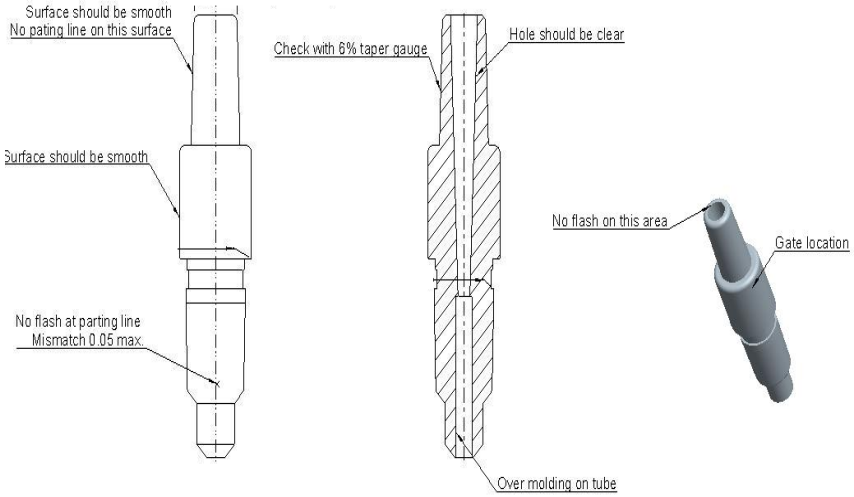
8.1.2 Assembly - Assembly of Extension Tube is done as per WI/MDS/04 in controlled environment conditions.

9. FUNCTIONAL SPECIFICATIONS

9.1 Extension Lines

9.1.1 Male Luer Connector

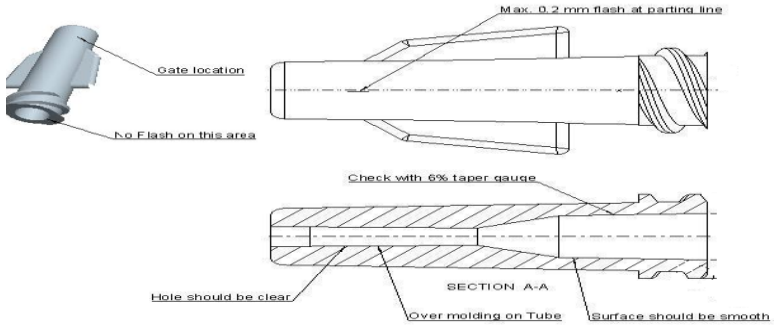
- Shall be transparent
- Designed to comply with ISO 8536-9:2015 & ISO 8536-10:2015.
- Shall be glued properly with tubing & must be 6% taper and must not show any leakage when connected with other devices as per EN 20594-1:1993/ AC-1997, EN 1707:1996 & ISO 80369-7:2016.



9.1.2 Female Luer Connector

- Shall be transparent.
- Designed to comply with ISO 80369-7:2016 / EN 1707:1996.
- The male point shall be 6% taper and must not show any leakage when connected with the female part, as per EN 20594-1:1993/ AC-1997, EN 1707:1996 & ISO 80369-7:2016.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head - QA		01.04.2020



9.1.3 PVC / PVC free Tubing

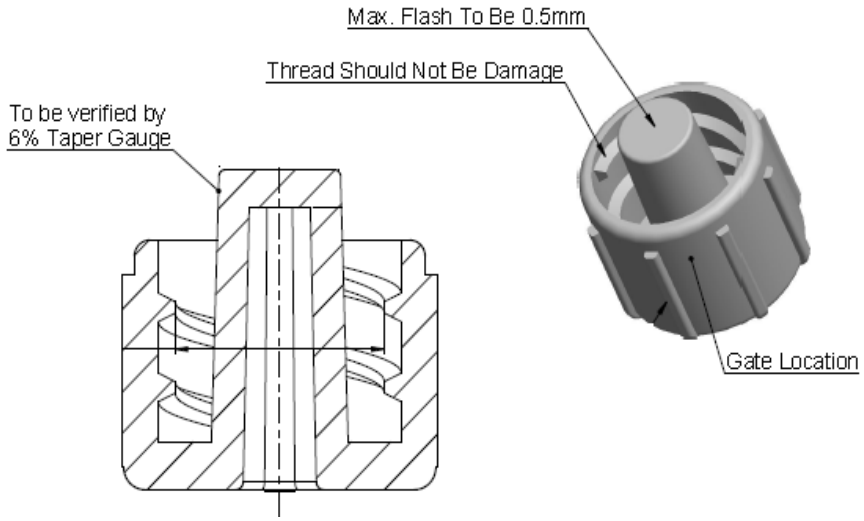
- The tubing shall be transparent or sufficiently translucent to monitor the passage of bubbles of air.
- The tubing at the joint of drip chamber is leak proof and must withstand specified static tensile force
- Hardness of Low-pressure PVC tubing should be- 75 to 77 Shore A.
- Hardness of High-pressure PVC tubing should be- 85 to 86 Shore A.
- Different tube dimensions are given below table:

Type of Tubes	*Inner Dimension*	*Outer Dimension*
High Pressure Extension Line (PVC)	1.00 ± 0.05 mm	3.00 ± 0.05 mm
Low Pressure Extension Line (PVC)	2.90 ± 0.05 mm	4.00 ± 0.05 mm
PVC Free (PE) High pressure Extension Line - Straight	1.00 ± 0.05 mm	2.00 ± 0.05 mm
PVC free (PE) High Pressure Extension Line - Coiled	1.00 ± 0.05 mm	2.00 ± 0.05 mm
Extension Tube with T-Type connector	1.15 +0.05/ -0.00 mm	1.90 +0.05/ -0.00 mm

9.1.4 Luer Lock Plug

- Also known as Luer Lock cap.
- Male Luer Lock design to comply with EN 20594-1:1993/ AC-1997 / ISO 80369-7:2016 / EN 1707:1996.
- External gripping features.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head - QA		01.04.2020



9.2 Packaging

9.2.1 Unit package bottom shall be a soft blister formed of PP+PE film, which should be clear, and this shall be sealed with a printed lid of medical grade, non-toxic lacquered paper.

9.2.2 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.

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

9.2.4 Hundred (100) pcs of unit packages shall be packed into one Inner Duplex printed cardboard box.

9.2.5 Ten (10) Duplex boxes shall be packed into one corrugated shipper box, as per customer requirement.

9.2.6 The combination of shipper box/duplex 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 ASSEMBLY OF PRODUCT

- 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/02.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head - QA		01.04.2020

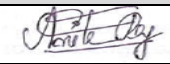
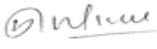
- The clean rooms are continuously monitored for environmental bio burden by using settling plate method. The bio burden method, frequency and limit of colony forming unit (CFU) are defined in GTP/QC/14.
- The bio burden on the equipment, fixture, dresses of workers etc is also frequently monitored. The bio burden method, frequency and limit of colony forming unit (CFU) are defined in GTP/QC/14.

11. CLASSIFICATION

- As per the "Classification criteria" Annexure- IX of the Council Directive 93/42/EEC as amended by 2007/47/EC the Extension lines are used for more than 60 minutes and less than 30 days. Hence this device is for 'short term use' as per the description in the 1.1 of Annexure- IX.
- This device does not penetrate inside the body, hence is "Non-invasive device".
- This device is used for channeling of intravenous fluids and other body liquids. So, Extension line is classified as **Class- IIa** medical device as per Rule- 2 of Classification criteria.

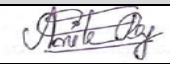
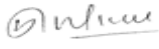
12. QUALITY PLAN

- A three tier Quality system 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/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.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head - QA		01.04.2020

REVISION SUMMARY

Supersedes	Effective Date	Reason for Review/Revision
02	12.09.2005	Revise to add product variants.
03	24.01.2007	Revise to add reference for EC Vigilance Procedure
04	05.01.2009	Reference for DEHP free tubing added
05	19.10.2010	Revise to update standard EN ISO 14971:2009.
06	11.01.2011	Change made in section 9 to add tube Hardness
07	16.09.2011	Change made in section 9 to add tube Dimensions
08	10.04.2013	Revise to update standard EN ISO 14971:2012 & EN ISO 15223-1:2012.
09	15.03.2014	Addition for the reference of Standards-Biological Evaluation EN ISO 10993.
10	11.07.2014	Revise to update sterilization parameter.
11	08.11.2014	Revise to add reference standard ISO 14644 (Part 1 to Part 8).
12	01.07.2015	Addition of revision summary
13	15.10.2015	Change made in clause 3 & 4.
14	03.11.2016	Change made in clause 4, 6 & 10.
15	*19.05.2017*	*Reference of standards updated*
16	*15.12.2017*	• *Product classification details as per EN ISO 10993-1:2009 added in Section 3.5.* • *Updated Section 4.0, reference documents to include latest version of applicable standards & segregated as harmonized and non-harmonized.* • *Updated sterilization parameters in Section 6.1.* • *Updated section 7.1, Material table to add CAS number.* • *Updated parameters in table in section 9.1.3.* • *Packaging information added in Section 9.2.*

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head - QA		01.04.2020