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MEDICAL DEVICES - COMPLIANCE FRAMEWORK FOR SMALL BORE CONNECTORS (LUERS) TOWARDS ISO 80369 STANDARD

WHITEPAPER

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1.0 Excerpts about paper

The chronological progression to adopt and recognize ISO 80369 series of standards from its antecedent ISO 594 series is now gradually transitioning into its implementation phase. The new series of standards are intended to have unique connector designs for each medical device application globally that are dimensionally driven and eliminates misconnection to unrelated healthcare applications.

“In the forefront, the U.S. Food and Drug Administration (FDA) will start to recognize the ISO 80369-7 standard by superseding their recognition towards ISO 594 standards. FDA will discontinue their acceptance of ISO 594 standard in support of premarket submissions until 31December2019. On the other hand, Japan’s PMDA (Pharmaceuticals and Medical Devices Agency) has mandated to switch the products to the new ISO 80369-6 standard by the end of February 2020 and ISO 80369-3 by the end of November 2021. The state of California has passed a bill that prohibits using an epidural, intravenous, or enteral feeding connector that fits into a connection port other than the type for which it was intended, effective from 01January2016.”

The medical device manufacturers across the globe are proactively involved in analyzing their products impact towards the new ISO 80369 standard. The connector manufacturers are meticulously focusing to accept the changes of ubiquitous new standard and started to develop plans for shifting in order to ensure patient safety and uphold global markets. This white paper brings down the step by step processes involved towards regulatory conformity of a small bore connector for the new series of ISO 80369 standard based on authors perception and understanding in the field.

2.0 Background- The Prelude to ISO 80369 series

Inadvertent Luer misconnections:

The widespread standard small bore connectors (commonly known as “Luers”) that are prominent in the medical device field for many years has been the Luer connectors. Luers have a long, rich history and a replicated future. A variety of drug delivery systems, medical devices and accessories use luer connectors to route and deliver medications to patients. Luer connectors effective and reliable design allows functional connection across different types of unrelated applications, such as vascular, enteral, respiratory, epidural and intrathecal. This instigated unintentional misconnections of connectors between incompatible devices and had a detrimental effect to patients’ health or even death.

Pursuit to halt wrong route mishaps:

Numerous reports from publications described umpteenth time of Luer misconnections, life-threatening occurrences and patient’s death over the past years. These incidents rendered to develop a ISO standard with a technological evolution and safety requirements. International Organization for Standardization (ISO) 594/1 and 594/2 standards were prepared by Technical Committee of “ISO/TC 84, Syringes for medical use and needles for injections”. IS0 594 standards specifies the requirements for conical fittings with a 6 % Luer taper for use with hypodermic syringes and needles and with certain other apparatus for medical use such as transfusion and infusion sets. This part of standard was somewhat reticent about unique connector designs for different medical applications.

Crux and Quintessential of Luer Standards:

With the same connector being used simultaneously in different healthcare applications, the possibility of misconnections between these applications will always pose a lethal threat. That’s why replacement with new standards mandating unique connector designs for different applications was acquainted. To mitigate this problem through an international consensus process, the International Organization for Standardization (ISO), the Association for the Advancement of Medical Instrumentation (AAMI), clinicians, the medical device industry manufacturers and regulators, including the U.S. Food and Drug Administration (FDA) are collaborating to reduce the likelihood of misconnections by creating a new industry standard: “ISO 80369 series”. ISO 80369 standard delineates unique design of small bore connectors for each delivery system type that interface with products specific to medical application. This standard was developed based on safety concerns, functional needs, to deter misconnections athwart clinical applications, extricated into reliable designs and processes.

3.0 Glimpses and Snippets

- **Misconnection:** Inappropriate connections occurring between two connectors that attach devices with different intended uses or applications.
- **Luer:** Luers are nothing but Small Bore Connectors that contains a conical mating surface with a 6 % (Luer) taper intended for use in applications of medical devices and related accessories for the purpose of delivering fluids or gases with an inner diameter of less than 8.5 mm. A Luer connector can either be a Luer Slip connector or a Luer Lock connector.
- **Non-interconnectable connectors:** Connectors that have geometries and other variable design characteristics that prevent secure and unintended connections.
- **ISO 594-1 (Superseded by ISO 80369 standards):** Luer Slip Connector-Luer connector without a lock (push fitting)
- **ISO 594-2 (Superseded by ISO 80369 standards)**: Luer Lock Connector-Luer connector that contains a locking mechanism (screw-in-threaded fitting)
- **ISO 80369-7:** Supersedes ISO 594-1:1986 and ISO 594-2:1998, clauses, subclauses, tables, figures, and annexes of which have been consolidated and technically revised.

4.0 The ISO 80369 Series- Proclaims for Intended Use

ISO 80369 is divided into eight sections. The ISO 80369-1 identifies the general requirements for small-bore connectors for different healthcare applications whereas ISO 80369-20 specifies the common test methods to evaluate the performance requirements, and the following six identify specific requirements for connectors falling into one of the following general healthcare application areas:

- **ISO 80369-1: General Requirements**
- ISO 80369-2: Breathing Systems and Driving Gases
- ISO 80369-3: Enteral (Feeding Tube) and Gastric
- ISO 80369-4: Urethral and Urinary
- ISO 80369-5: Limb Cuff Inflation or Non-Invasive Blood Pressure
- ISO 80369-6: Neuraxial Devices
- ISO 80369-7: Intravascular or Hypodermic (cancels and replaces ISO 594-1 and ISO 594-2)
- **ISO 80369-20: Common Test Methods**

The new small bore connector designs are dimensionally driven. The aim of ISO 80369 is to reduce the likelihood of adverse events by introducing unique connector designs for different medical applications whose design makes it extremely incompatible to connect with unrelated applications and promotes better patient safety. This reduces the chances of wrong route connections and the harm and death associated with these incidents.

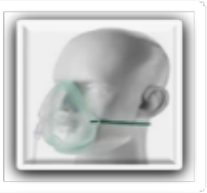
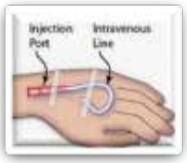
ISO 80369-1	Small bore connectors for liquids and gases in healthcare applications — Part 1: General requirements	**26 Nov 2018**	
ISO 80369-2	Small bore connectors for liquids and gases in healthcare applications — Part 2: Breathing systems and driving gases	**01 Sep 2015**	
ISO 80369-3	Small bore connectors for liquids and gases in healthcare applications — Part 3: Enteral	**31 Aug 2016**	
ISO 80369-4	Small bore connectors for liquids and gases in healthcare applications — Part 4: Urethral and Urinary	**Inactive**	
ISO 80369-5	Small bore connectors for liquids and gases in healthcare applications — Part 5: Limb Cuff Inflation	**30 Nov 2016**	
ISO 80369-6	Small bore connectors for liquids and gases in healthcare applications — Part 6: Neuraxial	**30 Apr 2016**	
ISO 80369-7	Small bore connectors for liquids and gases in healthcare applications — Part 7: Intravascular or Hypodermic	**01 Dec 2016**	
ISO 80369-20	Small bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods	**30 Jun 2015**	

Figure 1. ISO 80369 Standard and Applications with Release Date

5.0 Medical Device Manufacturers and Transition to ISO 80369

With ISO 80369 been recognized as the global standard for small bore connectors, medical device manufacturers are proactively involved in analyzing the impacts of their products and developing plans to prepare for the changes. The changes for the new standard connectors will be rolled out by delivery system, regulatory bodies or federal mandates. Manufacturers are advancing to adopt and incorporate the proposed design changes to the connectors per standard with minimal disruption to supply and clinical practice. The most critical and challenging part is to manage and control the lifecycle of existing connectors in the market.

Care should be taken in order to implement the changes without any impact to the existing products. There will be a phase-in period for product development and implementation guided by the FDA, and existing state legislation (Example: California).

“The standard generally allows three years to manufacturers for new product adoption of the new connector standards, and five years for adoption into existing devices. However, these timelines are influenced by state legislation”.

6.0 Implementation Strategy towards ISO 80369 Compliance

Identification of Luers

- By Therapy application
- By Sales Volume
- By Product Family
- By Country Impact
- By End of Life

Preliminary Dimensional Gap Assessment

- Investigate dimensional compliance status of part with respect to ISO 80369 standard
- Identify gaps of non-complying dimensions

Sample Measurement and Data Analysis

- Measure dimensions from physical samples
- Perform dimensional compliance analysis from measured and ISO 80369 standard values to arrive new/proposed dimensions for compliance

Final Dimensional Gap Assessment

- Summarize the proposed future dimensions of connectors that are in compliance with ISO 80369 standard
- Prepare a markup by designating proposed future dimensions in existing drawing

Documentation and Design Technical Review

- Report creation to document dimensional analysis results
- Conduct a design review meeting to finalize the proposed design changes

Implementation of changes

- Initiate the change control for drawing / mold change steel building activities per core team feedback
- Follow change control procedure for testing/ implementation and drawing release

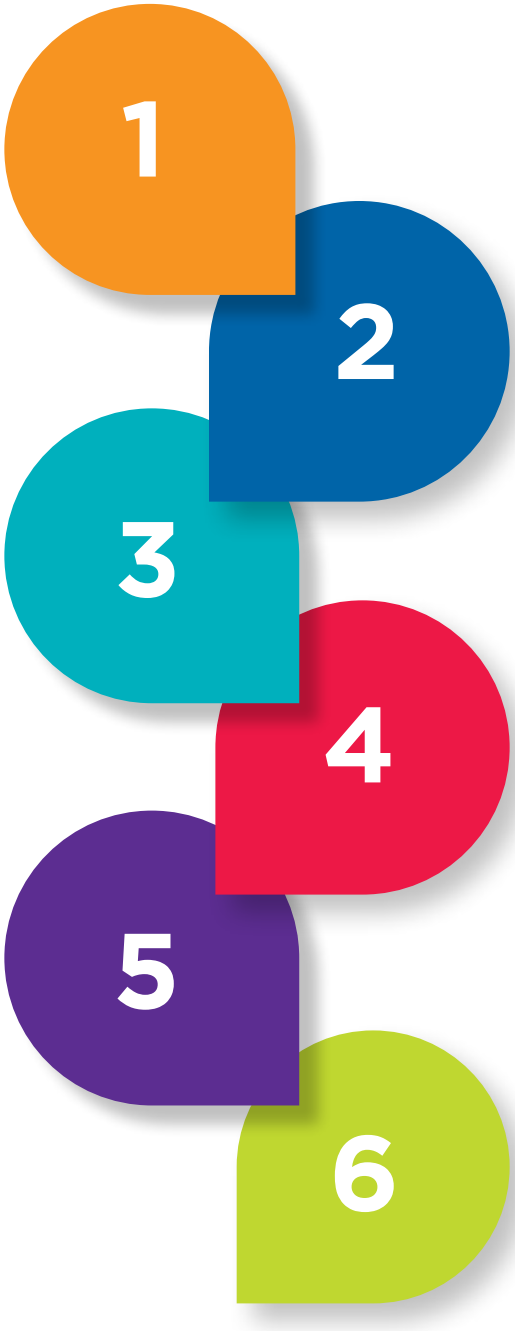


Figure 2. High Level Process Flow - Engineering Dimensional Gap Analysis and Change Implementation

6.1 Engineering Dimensional Gap Analysis

ISO 80369 specifies dimensions and requirements for the design and functional performance of small-bore connectors in each series of application. The predominant requirement for a connector is to be dimensionally compliant with its intended application of standard. Dimensional conformance to the figures and tables in the respective Annexes of standard will address this requirement. There are certain number of additional dimensions and tolerances that were not identified in the old ISO 594 standards are added to ISO 80369 series of standard. During regulatory submission, it is required to submit the evidence of the connector design conforming to the dimensional specifications of its intended application use. If the connector does not meet the specification, then it is prohibited as a connector per the intended application category.

The simplest and most effective way to comply dimensional requirement is to design and manufacture the connector within the prescribed dimensions and tolerances detailed in the standard. The alternative way would be a tedious and complex one, that involves non-interconnectability study involving multiple connector interference check and meeting performance requirements.

Below steps will be a guide to modify and update the existing part drawings towards dimensional compliance and implementation of ISO 80369 standard.

6.1.1 Identification of Luers for standard compliance

Small bore connectors that are presumed to undergo changes for standard compliance broadly falls under these two categories:

1. Change made with intent to significantly improve the safety or effectiveness of the device and
2. Technology, Engineering, and Performance Changes as per "Guidance for Industry and Food and Drug Administration Staff", document issued by FDA on October 25, 2017.

The first step for the manufacturers is to analyze the global market trend of each connector which are decided for compliance changes. They have to be prepared for the changes without afflicting the product use in healthcare facilities. With a clear forecast and plan, timeline has to be fixed to recall the existing connectors without compliance and replace with new connectors that are under compliance. Few aspects that shall be considered to scrutinize the connectors for standard compliance are (i) Based on Product Family, (ii) Based on Country Impact, (iii) Based on Sales Volume of Connector, (v) Based on Connector's End of Life and (vi) Based on application type.

6.1.2 Preliminary Dimensional Gap Assessment

To begin with the dimensional assessment, existing version of Part Drawing and CAD Model of the small bore connector under changes for standard compliance is retrieved from the repository. The assessment shall be carried out by identifying the right Luer type (Example: Male or Female Luer) from the Annex of the applicable version of ISO 80369 standard. It is recommended to list the ISO dimensions in a spreadsheet and populate the respective part drawing dimensions adjacently so as to identify the gaps and compliance status effectively. Additionally, a markup in the existing drawing shall be done to ensure the availability of ISO dimensions and to mark the missing dimensions or compliance dimensions which will be required to update in the future

version of drawing. Each ISO standard dimensions and tolerances are compared with existing part drawing to verify its state of compliance. If dimensions are unavailable from existing part drawing, dimensions can be measured from the equivalent existing CAD model for the assessment to compare with the standard. Dimensions are recommended to incorporate in the spreadsheet as well as a redline markup in the existing drawing. Dimensions that are in compliance with standard shall not require further assessments whereas dimensions that are not in compliance are to be investigated further towards compliance using physical current molded and manufactured parts that can be described in the next paragraph.

6.1.3 Sample Measurement and Data Analysis

There are possibilities for dimensional variations between the part drawing and physical samples due to manufacturing / molding process thus followed. Specifically, it can be observed in the connectors as parts are manufactured from different cavities of a mold and also across molds.

In this assessment, non-complying dimensions from the part drawing are measured in the physical molded samples to assess the dimensional qualification with standard dimensions. Total number of samples (sample size) to be measured are chosen and examined per manufacturers, Product design owner, Subject matter experts and molding engineers' direction and approach. Measurement techniques may be employed to assess a connector's dimensions based on manufacturers feasibility and level of accuracy anticipated, including Coordinate Measuring Machine (CMM), Computed Tomography (CT) scanning, Video Measuring System (VMS), basic measuring instruments etc., With the measurement results, sample dimensions are compared with ISO dimensions and verified for its compliance status. For sample dimensions that are within ISO standard dimensional range, it would be sufficient and preferable to modify the tolerances in the future drawing. On contrary, sample dimensions that aren't compliance will require to be proposed with new dimensions.

Depending on the impact and severity of non-complying dimension, separate dimensional analysis using CAD models and physical samples will need to be performed to arrive at new dimension in compliance. During this analysis, it is recommended to involve Design, Manufacturing, Mold Engineering, Quality and additional departments as required to finalize the new dimensions. Based on the dimensional analysis, discussion and feedback from cross-functional departments, non-complying dimension are proposed with new dimensions that are in compliance.

6.1.4 Final Dimensional Gap Assessment

Based on the Preliminary Dimensional Gap assessment(6.1.2) and Sample Measurement data analysis(6.1.3), the proposed design changes on the small bore connector shall be identified and finalized towards ISO standard dimensional requirements. The proposed dimensional changes are populated against each ISO dimensions and validated for its compliance state. Additionally, rationales or justifications to arrive on the proposed dimensions shall be noted. Finally, the proposed final dimensions for changes are designated as a markup in the existing drawing. By this, the tasks for dimensional gap assessment are completed by identifying the future drawing dimensions that are in ISO standard compliance. In general, Final dimensional gap assessment concludes with the revision of future drawing into below two categories:

1. **Drawing change:** Refers to proposed dimensions and tolerances are inline and within the range of existing drawing dimensions and tolerances. Also, refers to the proposed dimensions meet the tolerance range as prescribed in ISO 80369 standard.

2. **Mold steel change:** Refers to proposed dimensions and tolerances are outside the range of existing drawing dimensions and tolerances. Also, refers to the proposed dimensions that needs to be met with the tolerance range as prescribed in ISO 80369 standard and requires mold steel change or mold modification.

6.1.5 Documentation of Gap Analysis and Design Technical Review

As a vital part of regulatory requirement, it is mandatory to submit the changes made in the connector when a replacement to existing connector is introduced into market. As a regulatory need and to track the connector's change history, its required to document the Dimensional Gap Analysis results as a report. The dimensional compliance report shall include the results of the preliminary dimensional gap assessment, sample measurement analysis, drawing markups with appropriate rationales/justifications on the proposed design changes to the connector. This report is to be approved and released in a Product lifecycle management (PLM) or documented in repository.

Post documentation as a report, it is recommended to conduct a Design/ Technical Review Meeting by involving engineering, Quality, molding departments and other cross functional team as needed. In this meeting, the dimensional analysis results are discussed and reviewed for complications involved during implementation of changes in the drawing and/or steel molds. If any dimension is found to be impacting the design or molding steel validation process, it will be revised in a feasible way for implementation and also meeting ISO standard dimensional requirement. The Design/ Technical review meeting is concluded by agreeing on the proposed future dimensions of the connector for standard compliance. The meeting minutes should be documented, approved by the reviewers and released in a PLM or documented in repository as like report.

6.2 Implementation of Changes through CCM

Identified changes on the connector towards standard compliance as outlined in the Dimensional Compliance Report and Design Review Meeting shall be progressed and subjected for implementation through Change Control Management (CCM) Process. CCM will be an assertive process to track, control, monitor and record the lifecycle of the connector during the execution of changes, also for Regulatory Submission. Various PLM software's available in market which shall be utilized effectively to handle the CCM process. Few of them are namely, "CompliantPro, TrackWise, CloudEQMS, ideagen, Qualio, QT9-QMS, Vivaldi QMS and CodeLynx". PLM software is configured with systematic procedures to carry out and document the step by step processes involved in CCM as listed below.

- Change Control Initiation
- Change Control Assessments, Planning and Approval
- Change Execution
- Change Implementation
- Change Closure

A change control is initiated depending upon the proposed changes either Drawing change or Mold change with a defined scope, objective and description of change followed by specifying the existing design and proposed changes, impacted product codes, countries marketed/ impacted, regulatory affairs involved and timeline for implementation. In addition, suitable

rationale/justification for the implementation of changes needs to be detailed out during the change control initiation.

Below table shows the anticipated tasks with related summary details during Change Execution Phase. These tasks may vary depending upon the changes implied in the connectors towards standard compliance.

Execution Tasks	Work Summary
CAD Drawing Update	Update the proposed changes in existing CAD drawing (Preliminary Drawing-Not released into system)
Mold Modification and Validation	Build/validate mold as per preliminary drawing and follow qualification processes (Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ))
Sample Measurement	Measure the new samples per preliminary drawing
Verification and Validation	Verify and validate the drawing and mold per the proposed changes
Functional Testing per ISO 80369-20	Perform functional testing with new connector design and document the results for compliance

Table 1: Execution Tasks and Summary

Below table shows the anticipated tasks with related summary details during Change Implementation Phase. These tasks may vary depending upon the changes implied in the connectors towards standard compliance.

Documentation	Anticipated Changes in Design Control elements in DHF (Design History File)
Luer Requirements	System and Sub-system requirements update to meet with ISO 80369 standard requirements
Part Specifications and Drawings	Modify and release the BOM, part specification and drawings as per the proposed changes for standard compliance in system
Verification and Validation	Documents associated with Design Verification, Process validation (Mold/Testing) are modified and released
Risk	Risk Management Report and Risk Analysis reports are released
Biocompatibility	Documentation of Biocompatibility analysis
Clinical Report	Clinical evaluation report
Toxicology	Toxicology analysis and results documentation
Shelf Life study	Conduct stability test and release the study report
Material, Labelling and Packaging Specifications (If applicable)	Respective specifications are updated and released into system as required

Table 2: Implementation Task and Summary

6.3 Regulatory Submission:

The FDA, EU and other international regulatory bodies have their own requirements for acceptance and recognition of ISO 80369 standards.

Common submission process and procedures are listed as below,

- Small bore connectors met with ISO 80369 standard compliance are submitted to regulatory bodies or state medical legislations for approval and subsequent release into market.
- Regulatory bodies will acknowledge the proposal receipt for submission and notify the industry for review on the connector.
- Personnel's from regulatory will conduct a comprehensive review on the connector for its liability to utilize in healthcare centers. This review shall be conducted through meeting/ call/email by investigating all the records associated to the connector with the industry personnel.
- The connector is reviewed per the regulatory requirements for its acceptance and will be declared as accepted through a conclusion letter by the reviewer. Connector shall thus be marketed and put into for public use.

510(k) or Premarket submission to FDA:

Medical device establishments who wish to sell their connectors into U.S. markets, must submit for a 510(k) to FDA for clearance to demonstrate that their device is safe and effective for use.

A 510(k) submission is required when:

- Introducing a device into U.S. market newly
- Any change or modifications to a legally marketed device and that change could significantly affect its safety or effectiveness.

7.0 Regulations/Federal Mandates on ISO 80369 series (Few regions across the world)

January 1
2016

California (AB 444)

Prohibited from using an **Intravenous connector (ISO 80369-7)** that would fit into a connector other than the type it was intended

July 1
2016

California (AB 444)

Prohibited from using an **Enteral Feeding connector (ISO 80369-3)** that would fit into a connector other than the type it was intended

January 1
2017

California (AB 444)

Prohibited from using an **Epidural connector (ISO 80369-6)** that would fit into a connector other than the type it was intended

December 31
2019

U.S. (FDA)

Agency will accept declaration of conformity to **ISO 594 standards** in support of premarket submissions

February
2016

Japan (PMDA)

New products complying with **ISO 80369-6 standard** will be distributed on the Japanese market

November
2021

Japan (PMDA)

New products complying with **ISO 80369-3 standard** will be distributed on the Japanese market

CALIFORNIA MANDATES U.S. (FDA) JAPAN (PMDA)

Figure 3. Target dates for ISO 80369 Compliance in California State, U.S. (FDA) and Japan (PMDA)

7.1 U.S. FDA Regulation:

FDA has added ISO 80369-7 to its list of recognized consensus standards. The FDA website states that

"FDA will accept declaration of conformity, in support of premarket submissions, to ISO 594-1 and ISO 594-2 until December 31, 2019. After this transitional period, declaration of conformity to ISO 594-1 and ISO 594-2 will not be accepted".

7.2 Japan-PMDA (Pharmaceuticals and Medical Devices Agency) Regulations:

7.2.1 Pharmaceuticals and Medical Devices Safety Information No. 352 April 2018:

In Japan, the first-in-Japan introduction of the international standard for small-bore connectors is planned for neuraxial anesthesia among the product areas for which new standards have been established, and the Japanese Industrial Standards (JIS), which serve as the basis of the approval and certification standards of the new standard medical devices, have been revised as of February 1, 2018.

"It is expected that the new standard products complying with the new standard ISO 80369-6 will be distributed on the market as soon as required arrangements to ship such products are completed by their Marketing Authorization Holders (MAHs). In view of prompt switching to the new standard products in medical practice, the shipment of existing standard products by marketing authorization holders will be terminated by the end of the month 2 years after the date of revision of the JIS (i.e. the end of February 2020)".

7.2.2 Pharmaceuticals and Medical Devices Safety Information No. 366 September 2019:

In Japan's Ministry of Health, Labour and Welfare (MHLW), the introduction of the international standard for small-bore connectors is planned for enteral applications subsequently to neuraxial anesthesia among the product areas for which new standards have been established, and the Japanese Industrial Standards (JIS), which serve as the basis of the approval and certification standards of the new standard medical devices, have been revised as of May 1, 2018.

"From December 2019 onwards, the new standard products complying with the new standard ISO 80369-3 will be distributed to the market as soon as required arrangements to ship such products are completed by their Marketing Authorization Holders. In view of prompt switching to the new standard products in medical practice within a certain period, the shipment of old standard products by MAHs will be terminated by the end of the month 42 months after the date of the JIS revision (i.e. the end of November 2021)".

7.3 California Federal Mandates (Assembly Bills):

7.3.1 Assembly Bill (HB 1867):

"Extends, until January 1, 2016, the implementation date of a prohibition on the use of an epidural, intravenous, or enteral feeding connector that fits into a connection port other than the type for which it was intended. Under current law, for intravenous and enteral feeding connectors, this prohibition is scheduled to take effect on January 1, 2013, while the prohibition on these types

of epidural connectors is scheduled to take effect on January 1, 2014".

7.3.2 Assembly Bill (AB 444):

"Existing law, as of January 1, 2016, prohibits a health facility, as defined, from using an epidural connector or an enteral feeding connector, that would fit into a connector other than the type it was intended for, unless an emergency or urgent situation exists and the prohibition would impair the ability to provide health care.

This bill would make the provisions relating to an epidural connector operative as of January 1, 2017, and would make the provisions relating to an enteral feeding connector operative as of July 1, 2016. The bill would make conforming changes".

The AAMI expects that all medical device manufacturers and suppliers will comply with the new California law, and develop modified products that incorporate the new connectors and phase out products with old connectors.

8.0 Conclusion

A 110-years long, traditional Luers in the medical device field is all set to revamp into unique designs for intended applications and originate as Small Bore Connectors through ISO 80369 series of new standards. The current design of Luers as per ISO 594-1 and ISO 594-2 standard will get abandoned in future and designate its resumption as Small Bore Connectors per ISO 80369 series of standards. Assuring patient safety and minimalizing the risk of misconnection across medical device applications, federal and regulatory bodies have started to recognize and mandate the ISO 80369 standard compliance in Small Bore Connectors.

Compliance to ISO 80369 standard will definitely testify and challenges all the medical device manufacturers in smoothly switching over to this new standard and cope up with their existing markets. With seven parts/sections of ISO 80369 standard and each in different release status/ mandates, medical industries will need to gradually transform their existing connector into new unique designs for compliance.

As a whole, this white paper simplifies to understand the processes involved in the implementation of ISO 80369 standard compliance in small bore connectors (also known as Luer connector) for different healthcare applications by medical products manufacturers and also covers few of the federal and regulatory mandates. This paper covers the minimum recommended steps required to be carried out to comply with the ISO 80369 standard design requirements for connectors, starting from engineering analysis to implementation of proposed changes in existing/new small bore connectors through change control management based on authors perception and understanding.

9.0 References

- https://www.fda.gov/default.htm
- https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k#who
- http://www.mddionline.com/
- https://www.iso.org/home.html
- http://stayconnected.org/frequently-asked-questions/
- http://www.medicaldesignbriefs.com/component/content/article/mdb/features/22072
- https://elsmar.com/elsmarqualityforum/threads/plunger-rod-for-syringe-is-there-a-standard-for-piston-rods.76369/
- http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB444
- http://www.leginfo.ca.gov/pub/11-12/bill/asm/ab_1851-1900/ab_1867_cfa_20120604_115453_sen_comm.html
- http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0016.html
- https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0017.html
- https://www.techbriefs.com/component/content/article/mdb/features/articles/22072?start=2
- https://www.ecnmag.com/article/2014/11/iso-80369-standards-small-bore-tubing-connectors-inch-forward-toward-release
- https://docplayer.net/amp/136066756-Iso-series-contributing-to-standard-development-nsai-workshop-linda-hendy-standard-officer-nsai-standard-development-26-th-march-20-19.html
- https://www.ddltesting.com/blog/iso-80369-7-changing-the-standard-for-luer-connectors/
- https://www.medicalplasticsnews.com/mpn-north-america/setting-the-standard/
- https://www.nordsonmedical.com/products/iso_80369_article.aspx
- Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications.pdf
- Evaluating the risk of device Misconnections-Designing for medical devices with ISO 80369 in mind.pdf
- FDA_SafetyDeviceCalendar_edited.pdf

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Kavin Karthick S has a Master degree in Thermal Engineering. He has over 6 years of experience in Medical Domain, of which 4 years of experience in Engineering Analysis of Small Bore Connectors towards ISO 80369-7 standard compliance process for Class II medical devices and been a part of Implementation of design changes through Change Control. He is also familiar in ISO 594-1/2, ISO 80369 series standards and Verification of Small Bore Connectors by means of performance test methods as per ISO 80369-20. His previous work experience was into the field of Product Design and Development, to execute and record engineering calculations of Cross Flow Heat Exchanger, Air dryers (Heatless, Heated Purge, Blower Regenerated, Heat of Compression, No Loss Split Flow and Refrigerated), Air Filters and Air Receivers (Pressure vessel).

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