nutrisafe2

compliant with ISO 80369-1:2010

BACKGROUND

Medical tubing misconnections impact patients, caregivers, institutions, manufacturers, and regulatory agencies and are a huge concern for all involved. Much attention has been given to this topic, especially recently, due to a number of factors including cases of patient death or injury from misconnections, as well as legislation recently passed in California that requests the end-users to adopt safety enteral, epidural and intravenous systems.

In that context, an ISO committee has been built up to work on the standard about small-bore connectors for liquids and gases in healthcare applications.

This series of standards is the ISO 80369.

While each of the sub-part of this standard is dedicated to different fields in healthcare, the first part (ISO 80369-1) provides the methodology to assess non-interconnectable characteristics of small-bore connectors based on their inherent design and dimensions in order to reduce the risk of misconnections between medical devices or between accessories for different applications.

The ISO team conducted a dimensional analysis where all proposed enteral connector designs were compared, in CAD (Computer Aided Design), against existing standards for other connectors and against proposed connector designs for other applications within the ISO 80369 series. Matrix and methodology developed within this work group has been used in this report.

1/ Objective

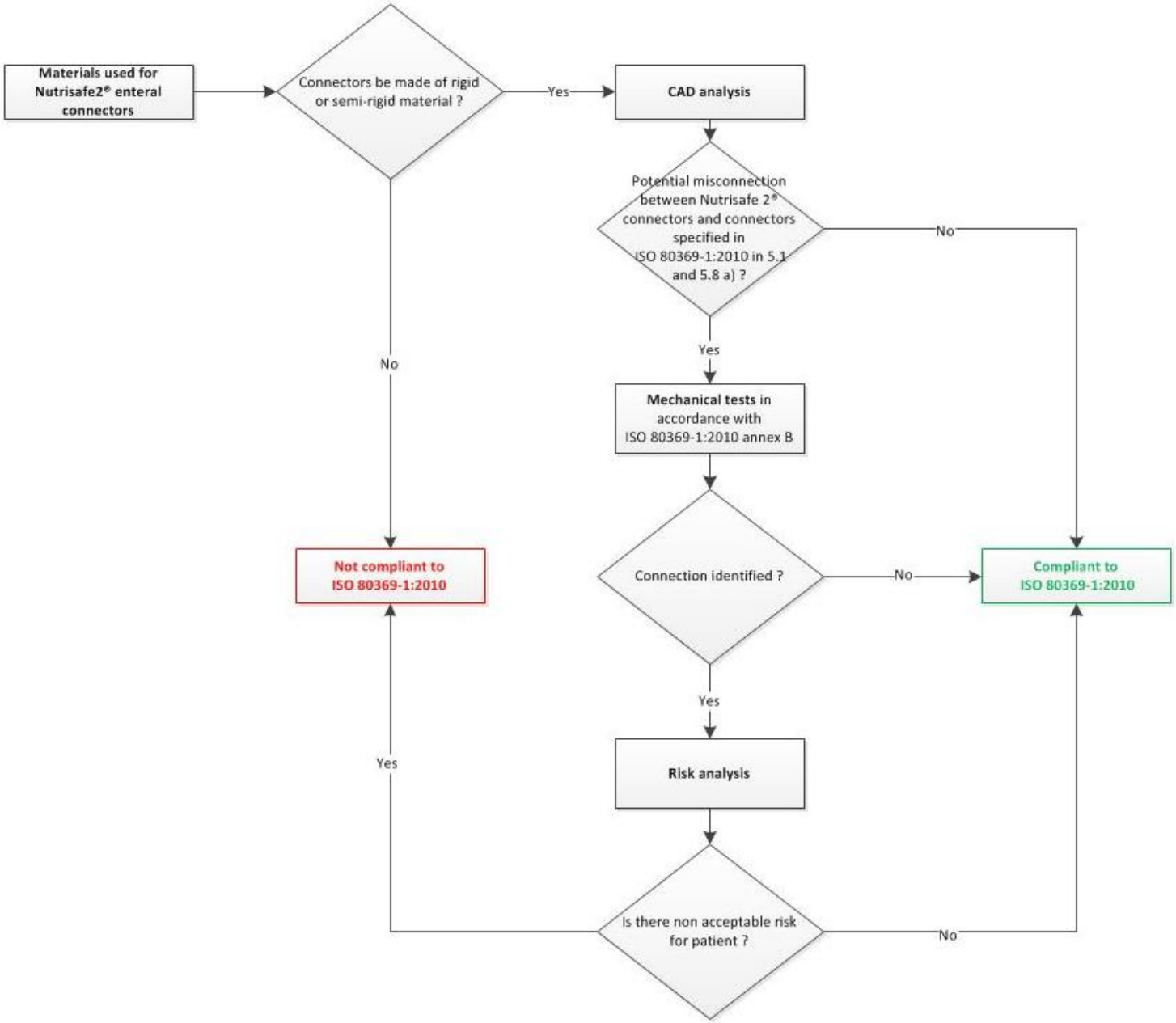
The objective is to study the compliance of the Nutrisafe2 connector developed by VYGON to the standards ISO80369-1:2010. In particular:

- To check the conformity of the raw material used
- To check the reduction of the risks of misconnections with connectors outlined in the ISO80369-1:2010

This last part about misconnections assessment has been implemented through:

- Dimensional/CAD analysis study ;
- Mechanical testing according the annex B of the ISO80369-1:2010;
- Nutrisafe2 connector misconnection risk analysis.

The flow-chart detailing the way the study was done is on the following page.


Materials used for Nutrisafe2® enteral connectors
Connectors be made of rigid or semi-rigid material ?
Yes
CAD analysis
Potential misconnection between Nutrisafe 2® connectors and connectors specified in ISO 80369-1:2010 in 5.1 and 5.8 a) ?
No
Yes
Mechanical tests in accordance with ISO 80369-1:2010 annex B
No
Not compliant to ISO 80369-1:2010
Connection identified ?
No
Compliant to ISO 80369-1:2010
Yes
Risk analysis
Yes
Is there non acceptable risk for patient ?
No

2/ COMPLIANCE STUDY

2.1 Materials used for Nutrisafe2 enteral small-bore connectors

In accordance with §4 of ISO 80369-1:2010, Nutrisafe2 small-bore connector must be made of rigid or semi-rigid material.

The modulus in tension of each material of Nutrisafe2 connectors has been checked according to ISO 80369-3: 2016, by applying the test of ASTM D638.

2.2 CAD analysis

The purpose is to identify where potential connections may exist between Nutrisafe2 connectors and connectors specified in ISO 80369-1:2010 in 5.1 and 5.8 a).

An analysis was performed to assess if a connection is made by an outside diameter (OD) of one connector fitting into and interfering with an inside diameter (ID) of another connector.

If a connection is possible then mechanical tests were realized (see §2.3).

No distinction was made between male or female connectors or direction of fluid flow at this point, i.e. same gender connections were assessed equal to opposite gender connections.

2.3 Mechanical tests

The mechanical tests were performed in accordance with ISO 80369-1:2010 annex B.

2.4 Risk analysis

A risk analysis has been performed according to our internal procedure, based on the NF EN ISO 14971:2013.

For this risk analysis, the direction of flow and the clinical application of the connectors were taken into account.

CONCLUSION

Considering the whole data provided during this analysis, the non-interconnectable characteristics of the Nutrisafe2 connectors have been demonstrated.

For that reason, Nutrisafe2 is compliant with ISO 80369-1:2010 - § 5.8 Alternative small-bore connectors.