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AMENDMENT 1
2019-02

**Small-bore connectors for liquids and
gases in healthcare applications —**

**Part 3:
Connectors for enteral applications**

AMENDMENT 1

*Raccords de petite taille pour liquides et gaz utilisés dans le domaine
de la santé —*

Partie 3: Raccords destinés à des applications entérales

AMENDEMENT 1

ISO 80369-3:2016/Amd 1:2019

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC 62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

A list of all the parts in the ISO 80369 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Small-bore connectors for liquids and gases in healthcare applications —

Part 3: Connectors for enteral applications

AMENDMENT 1

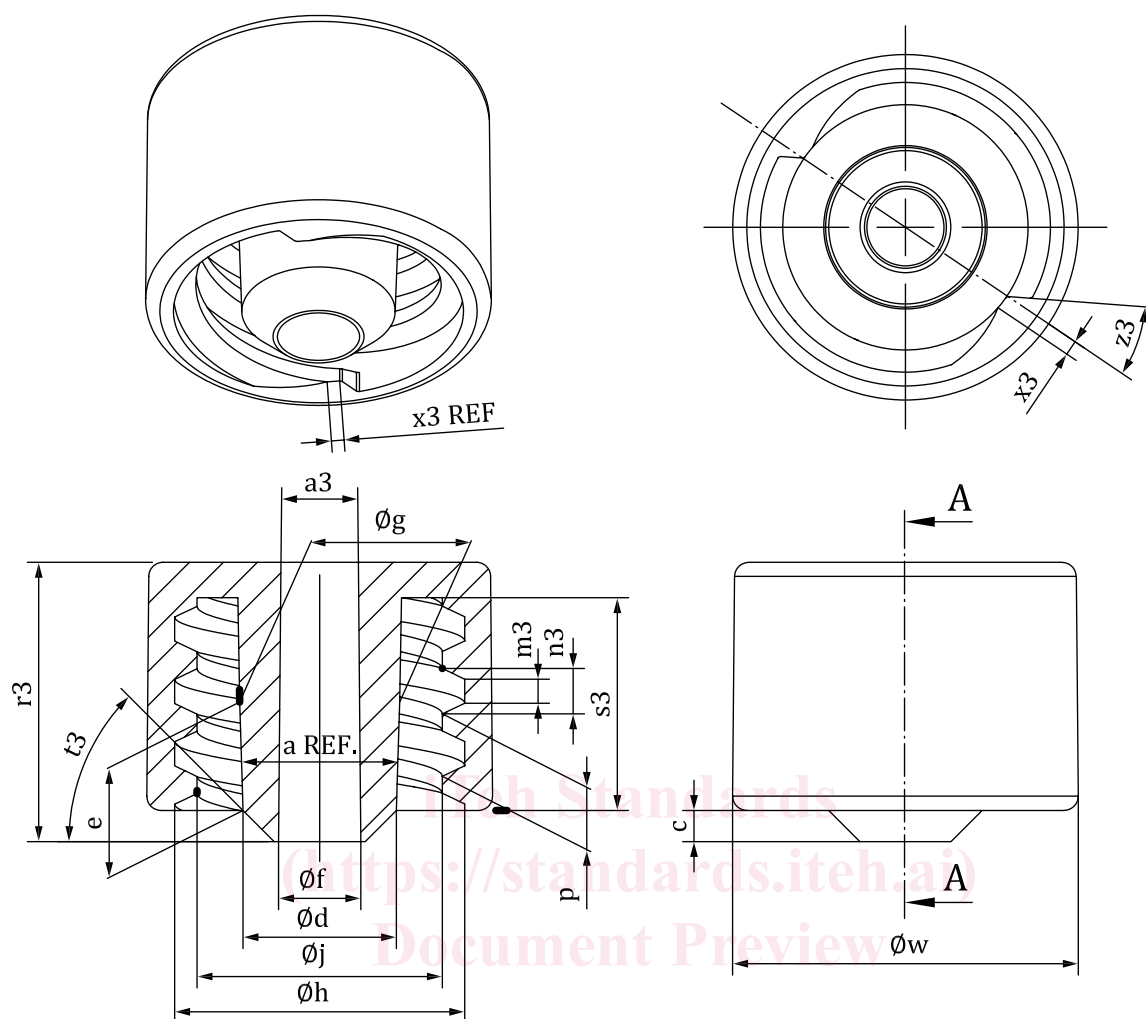
Scope

Remove the following text from the bulleted list under “This part of ISO 80369 does not specify requirements for SMALL-BORE CONNECTORS that are used for the following:”

“MEDICAL DEVICES for rectal drainage, rectal administration of medicines or fluid, and any other rectal access MEDICAL DEVICE”

Figure B.1

Revise Figure B.1 to add new dimension a_3 and r_3 and add a new NOTE 2.



NOTE 1 Table B.1 contains the dimensions for Figure B.1.

NOTE 2 Dimensions a_3 and r_3 start at $\emptyset f$.

Figure B.1 — Male E1 SMALL-BORE CONNECTOR

In Figure B.1, the male ENTERAL SMALL-BORE CONNECTOR may utilize a rotatable collar. The requirements for dimension c shall be maintained.

Table B.1

Revise Table B.1 as follows:

Add superscript "g" to $\emptyset f$.

Add a footnote "g" applicable to designations $\emptyset f$, a_3 and r_3 , "A minimum diameter of 2,85 for $\emptyset f$, a maximum angle of 2° for a_3 and a minimum depth of 8,00 for r_3 may be required in order to interface with certain finished devices".