DRAFT AMENDMENT ISO 80369-3:2016/DAM 1

ISO/TC **210**

Voting begins on: **2017-02-24**

Secretariat: ANSI

Voting terminates on: 2017-05-18

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: .

ICS: 11.040.25

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<u>ISO 80369-3:2016/DAmd 1</u> https://standards.iteh.ai/catalog/standards/sist/c2456384-3504-4ad4-904b-248e576466cc/iso-80369-3-2016-damd-1

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

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ISO/CEN PARALLEL PROCESSING



Reference number ISO 80369-3:2016/DAM 1:2017(E)

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Foreword

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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/DAmd 1 https://standards.iteh.ai/catalog/standards/sist/c2456384-3504-4ad4-904b-

ISO 80369 consists of the following parts; under the general title Small-bore connectors for liquids and gases in healthcare applications:

- Part 1: General requirements
- Part 2: Connectors for breathing systems and driving gases applications
- Part 3: Connectors for enteral applications
- Part 5: Connectors for limb cuff inflation applications
- Part 6: Connectors for neuraxial applications
- Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications
- Part 20: Common test methods

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

Part 3: Connectors for enteral applications

AMENDMENT 1:.

1 Modification to 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"

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