

INTERNATIONAL
STANDARD

ISO
18250-3

First edition
2018-06

**Medical devices — Connectors
for reservoir delivery systems for
healthcare applications —**

**Part 3:
Enteral applications**

*Dispositifs médicaux — Connecteurs pour systèmes de livraison de
réservoir pour des applications de soins de santé —*

Partie 3: Applications entérales



Reference number
ISO 18250-3:2018(E)

© ISO 2018



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	iv
Introduction	v
1 *Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	2
4.1 NON-INTERCONNECTABLE characteristics	2
4.2 *Materials	2
5 *Dimensional requirements	3
6 Performance requirements	3
6.1 General performance requirements	3
6.2 Positive pressure liquid leakage	3
6.3 Subatmospheric-pressure air leakage	3
6.4 Stress cracking	4
6.5 Resistance to separation from axial load	4
6.6 Resistance to separation from unscrewing	4
6.7 Resistance to overriding	4
6.8 Disconnection by unscrewing	4
Annex A (informative) Rationale and guidance	5
Annex B (normative) ENTERAL RESERVOIR CONNECTORS	6
Annex C (normative) Reference CONNECTORS	17
Annex D (informative) Assessment of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION	23
Annex E (informative) Summary of the usability requirements for RESERVOIR CONNECTORS for ENTERAL APPLICATIONS	24
Annex F (informative) Summary of RESERVOIR CONNECTOR criteria and requirements for ENTERAL APPLICATIONS	28
Annex G (informative) Summary of assessment of the design of the reservoir connectors for enteral applications	31
Annex H (informative) Deviations from ISO 80369-20	36
Annex I (informative) Twist-lock CONNECTOR geometric layout and functioning	37
Bibliography	39