

INTERNATIONAL
STANDARD

ISO
11238

Second edition
2018-07

**Health informatics — Identification
of medicinal products — Data
elements and structures for the
unique identification and exchange of
regulated information on substances**

*Informatique de santé — Identification des produits médicaux —
Eléments de données et structures pour l'identification unique et
l'échange d'informations réglementées sur les substances*



Reference number
ISO 11238:2018(E)



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	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Symbols and abbreviated terms	14
5 Description of the information modelling principles and practices	17
5.1 General considerations	17
5.2 Conceptual overview diagrams	17
5.3 Section high-level diagrams	18
5.4 Detailed diagrams	18
5.5 Relationships between classes	19
5.6 Notes	21
5.7 Attributes	21
5.8 Message exchange format	21
5.9 Conformance terminology and context as it relates to ISO 11238 and ISO/TS 19844	22
6 Requirements	22
6.1 General	22
6.2 Concepts required for the unique identification and description of substances	22
6.3 Concepts required for the description of specified substances	24
6.3.1 Relationship between Substances and Specified Substance Groups	26
6.4 Naming of substances	27
6.5 Requirements for unique identifiers	28
6.6 Existing identifiers and molecular structure representation	28
7 Types of substances	29
7.1 General	29
7.2 Element sets common to multiple types of substances	29
7.2.1 Structure	29
7.2.2 Isotope	29
7.2.3 Modification	30
7.2.4 Reference information	31
7.2.5 Source material	32
7.2.6 Taxonomy	33
7.2.7 Authentication of Herbal Drugs	33
7.2.8 Substance codes	34
7.3 Chemical substances	34
7.4 Protein substances	35
7.5 Nucleic acid substances	37
7.6 Polymer substances	38
7.7 Structurally diverse substances	39
7.8 Mixture	42
8 Defining specified substances	43
8.1 General	43
8.2 Specified Substance Group 1	44
8.3 Specified Substance Group 2	47
8.4 Specified Substance Group 3	49
8.5 Specified Substance Group 4	50
8.5.1 General	50
8.5.2 Specified Substance Group 4 Name	50
8.5.3 Grade	51
8.5.4 Use of analytical data	51