DIN EN ISO 11238:2018-11 (E)

Health informatics - Identification of medicinal products - Dat a elements and structures for the unique identification and exchange of regulated information on substances (ISO 11238:2018)

Contents

Page

European foreword ... **4**

Foreword ... **5**

Introduction ... **6**

1 Scope ... **8**

2 Normative references ... **8**

3 Terms and definitions ... **8**

4 Symbols and abbreviated terms ... **21**

5 Description of the information modelling principles and practices ... **24**
5.1 General considerations ... 24
5.2 Conceptual overview diagrams ... 24
5.3 Section high-level diagrams ... 25
5.4 Detailed diagrams ... 25
5.5 Relationships between classes ... 26
5.6 Notes ... 28
5.7 Attributes ... 28
5.8 Message exchange format ... 28
5.9 Conformance terminology and context as it relates to ISO 11238 and ISO/TS 19844 ... 29

6 Requirements ... **29**
6.1 General ... 29
6.2 Concepts required for the unique identification and description of substances ... 29
6.3 Concepts required for the description of specified substances ... 31
6.3.1 Relationship between Substances and Specified Substance Groups ... 33
6.4 Naming of substances ... 34
6.5 Requirements for unique identifiers ... 35
6.6 Existing identifiers and molecular structure representation ... 35

7 Types of substances ... **36**
7.1 General ... 36
7.2 Element sets common to multiple types of substances ... 36
7.2.1 Structure ... 36
7.2.2 Isotope ... 36
7.2.3 Modification ... 37
7.2.4 Reference information ... 38
7.2.5 Source material ... 39
7.2.6 Taxonomy ... 40
7.2.7 Authentication of Herbal Drugs ... 40
7.2.8 Substance codes ... 41
7.3 Chemical substances ... 41
7.4 Protein substances ... 42
7.5 Nucleic acid substances ... 44
7.6 Polymer substances ... 45
7.7 Structurally diverse substances ... 46
7.8 Mixture ... 49

8 Defining specified substances **50**
8.1 General 50
8.2 Specified Substance Group 1 51
8.3 Specified Substance Group 2 54
8.4 Specified Substance Group 3 56
8.5 Specified Substance Group 4 57
8.5.1 General 57
8.5.2 Specified Substance Group 4 Name 57
8.5.3 Grade 58
8.5.4 Use of analytical data 58
8.5.5 Manufacturing 59
8.5.6 Version and specification 59
Annex A (informative) **Existing identifiers and molecular structure representations** **63**
Bibliography **67**