ISO 18374:2025-04 (E)

Dentistry - Artificial intelligence (AI) and augmented intelligence (AuI) based 2D radiograph analysis - Data generation, data annotation and data processing

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 1
3.1 Artificial intelligence (AI) and its components 1
3.2 Machine learning techniques 2
3.3 Data processing and privacy 2
3.4 Data annotation and labelling 3
3.5 Dataset management 3
3.6 Assessment and evaluation 4

4 Abbreviated terms 4

5 General 4

6 Requirements 4
6.1 Data 4
6.1.1 Quantity, scope and handling of data 4
6.1.2 Quality control 5
6.1.3 Factors for the bias analysis 5
6.1.4 Input (training, testing and validation) data 5
6.1.5 Data validation 5
6.1.6 Data protection 5
6.1.7 Data protection control 5
6.2 Data annotation (labelling) 6
6.2.1 Annotation strategy 6
6.2.2 Annotation procedure 6
6.2.3 Competence 6
6.3 Data pre-processing 6
6.3.1 Pre-processing the data 6
6.3.2 Risks of data processing 6
6.4 Data post-processing 6

7 Test method 6
7.1 General 6
7.2 Data 7
7.2.1 Quantity and scope 7
7.2.2 Inclusion and exclusion criteria 7
7.2.3 Quality control 7
7.2.4 Factors for the bias analysis 7
7.2.5 Input data 8
7.2.6 Data validation 8
7.2.7 Data protection 9
7.2.8 Data protection control 9
7.3 Data annotation (labelling) 10
7.3.1 Annotation strategy 10

7.3.2 Annotation procedure 10
7.3.3 Competence 10
7.4 Data pre-processing 11
7.4.1 General 11
7.4.2 Risks of data processing 11

8 Test report 11

9 Electronic instructions for use 12

Bibliography 13