

DIN EN ISO 4823:2025-09 (E)

Dentistry - Elastomeric impression and bite registration materials (ISO 4823:2025)

Contents		Page
Foreword		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Classification	2
5	Requirements	2
5.1	Component colours (not applicable for transparent materials)	2
5.2	Mixing time (hand-spatulated or hand-kneaded mixes)	3
5.3	Consistency	3
5.4	Working time	3
5.5	Detail reproduction	3
5.6	Linear dimensional change	3
5.7	Compatibility with gypsum	3
5.8	Elastic recovery	3
5.9	Strain in compression	3
5.10	Minimum time in the oral cavity for bite registration materials	3
5.11	Compression set of bite registration materials	3
5.12	Hardness of bite registration materials	3
6	Pre-test planning approaches	4
6.1	General	4
6.2	Sampling	4
6.3	Pre-test product examinations	4
6.3.1	General	4
6.3.2	Examinations for conformity with labelling requirements	4
6.3.3	Examinations for effectiveness of the packaging	5
6.3.4	Examinations for compliance with requirements for instructions for use	5
6.4	Essential pre-test preparatory practices	5
6.4.1	Laboratory conditions	5
6.4.2	Apparatus function verification steps	5
6.4.3	Volume of materials to be mixed for each specimen	5
6.4.4	Proportioning, mixing and handling of hand-mixed materials to be tested	6
6.4.5	Timing for the specimen preparation and test procedures	6
6.4.6	Simulated oral time/temperature treatment of specimens formed in completely closed mould assemblies	6
6.5	Pass/fail determinations	6
6.6	Expression of test results	6
7	Test methods	6
7.1	Mixing time	6
7.1.1	Apparatus	6
7.1.2	Specimen preparation and test procedure (five specimens)	6
7.1.3	Pass/fail determination and expression of results	6
7.2	Consistency	7
7.2.1	Apparatus and materials	7
7.2.2	Advance preparation steps	7
7.2.3	Specimen preparation and test procedure (five specimens)	7
7.2.4	Pass/fail determination and expression of results	8
7.3	Working time	8
7.3.1	Apparatus	8
7.3.2	Working time test	9

7.4	Detail reproduction.....	10
7.4.1	Apparatus and materials	10
7.4.2	Specimen preparation	10
7.4.3	Test procedure.....	11
7.4.4	Pass/fail determination and expression of results.....	11
7.5	Linear dimensional change	11
7.5.1	Apparatus and materials	11
7.5.2	Test block line-length measurement procedure	11
7.5.3	Specimen preparation	12
7.5.4	Test specimen measurement.....	12
7.6	Compatibility with gypsum	13
7.6.1	Apparatus and materials	13
7.6.2	Specimen preparation	14
7.6.3	Test procedure.....	14
7.6.4	Pass/fail determination and expression of results.....	14
7.7	Elastic recovery	14
7.7.1	Apparatus and materials	14
7.7.2	Specimen preparation	15
7.7.3	Test procedure.....	15
7.7.4	Calculation of results.....	16
7.7.5	Pass/fail determination and expression of results.....	16
7.8	Strain in compression.....	16
7.8.1	Apparatus.....	16
7.8.2	Specimen preparation	16
7.8.3	Test procedure.....	16
7.8.4	Calculation of results.....	17
7.8.5	Pass/fail determination and expression of results.....	17
7.9	Minimum time in the oral cavity and compression set for bite registration materials.....	17
7.9.1	Apparatus	17
7.9.2	Specimen preparation	17
7.9.3	Test procedure.....	17
7.9.4	Evaluation.....	17
7.9.5	Pass/fail determination and expression of results.....	18
7.10	Hardness of bite registration materials.....	18
7.10.1	Apparatus	18
7.10.2	Specimen preparation	18
7.10.3	Test procedure.....	18
7.10.4	Evaluation.....	18
7.10.5	Pass/fail determination and expression of results.....	18
8	Requirements for labelling and instructions supplied by the manufacturer	19
8.1	Labelling requirements	19
8.2	Instructions for use.....	19
8.2.1	General	19
8.2.2	For all materials covered by this document.....	20
8.2.3	For all impression materials.....	20
8.2.4	Additional instructions	20
	Annex A (normative) Figures	22
	Annex B (normative) Standardized hand mixing methods.....	30
	Bibliography.....	33