

DIN EN ISO 4823:2021-06 (E)

Dentistry - Elastomeric impression and bite registration materials (ISO 4823:2021)

Contents		Page
European foreword		4
Foreword		5
1	Scope	6
2	Normative references	6
3	Terms and definitions	6
4	Classification	7
5	Requirements	8
5.1	Packaging requirements	8
5.2	Labelling requirements	8
5.2.1	Outer packages (containing one or more primary containers)	8
5.2.2	Primary containers within outer packaging	8
5.3	Requirements for information in the manufacturer's instructions	9
5.3.1	General	9
5.3.2	Identifying information	9
5.3.3	Specific instructions for use	9
5.4	Requirements for characteristics and properties	10
5.4.1	Component colours (hand-spatulated or hand-kneaded mixes)	10
5.4.2	Mixing time (hand-spatulated or hand-kneaded mixes)	10
5.4.3	Consistency	10
5.4.4	Working time	10
5.4.5	Detail reproduction	10
5.4.6	Linear dimensional change	10
5.4.7	Compatibility with gypsum	10
5.4.8	Elastic recovery	10
5.4.9	Strain in compression	10
5.4.10	Minimum time in the oral cavity for bite registration materials	11
5.4.11	Compression set of bite registration materials	11
5.4.12	Hardness of bite registration materials	11
6	Pre-test planning approaches	11
6.1	Sampling	11
6.2	Pre-test product examinations	12
6.2.1	Examinations for compliance with labelling requirements	12
6.2.2	Examinations for effectiveness of the packaging	12
6.2.3	Examinations for compliance with requirements for instructions for use	12
6.3	Essential pre-test preparatory practices	12
6.3.1	Laboratory conditions	12
6.3.2	Apparatus function verification steps	13
6.3.3	Volume of materials to be mixed for each specimen	13
6.3.4	Standardized approaches to proportioning, mixing, and handling of hand mixed materials to be tested	13
6.3.5	Timing for the specimen preparation and test procedures	13
6.3.6	Simulated oral time/temperature treatment of specimens formed in completely closed mould assemblies	13
6.4	Pass/fail determinations	13
6.5	Expression of test results	13

7	Testmethods--Specific	13
7.1	Mixing time	13
7.1.1	Apparatus	13
7.1.2	Specimen preparation and test procedure (five specimens)	14
7.1.3	Pass/fail determination and expression of results	14
7.2	Consistency	14
7.2.1	Apparatus and materials	14
7.2.2	Advance preparation steps	14
7.2.3	Specimen preparation and test procedure (5 specimens)	15
7.2.4	Pass/fail determination and expression of results	15
7.3	Working-time	15
7.3.1	Apparatus	15
7.3.2	Working time test	16
7.4	Detail reproduction	17
7.4.1	Apparatus and materials	17
7.4.2	Specimen preparation	17
7.4.3	Test procedure	18
7.4.4	Pass/fail determination and expression of results	18
7.5	Linear dimensional change	18
7.5.1	Apparatus and materials	18
7.5.2	Test block line-length measurement procedure	19
7.5.3	Specimen preparation	19
7.5.4	Test specimen measurement	19
7.6	Compatibility with gypsum	20
7.6.1	Apparatus and materials	20
7.6.2	Specimen preparation	21
7.6.3	Test procedure	21
7.6.4	Pass/fail determination and expression of results	21
7.7	Elastic recovery	22
7.7.1	Apparatus and materials	22
7.7.2	Specimen preparation	22
7.7.3	Test procedure	23
7.7.4	Calculation of results	23
7.7.5	Pass/fail determination and expression of results	23
7.8	Strain in compression	23
7.8.1	Apparatus	23
7.8.2	Specimen preparation	24
7.8.3	Test procedure	24
7.8.4	Calculation of results	24
7.8.5	Pass/fail determination and expression of results	24
7.9	Minimum time in the oral cavity and compression set for bite registration materials	24
7.9.1	Apparatus	24
7.9.2	Specimen preparation	24
7.9.3	Test procedure	24
7.9.4	Evaluation	25
7.9.5	Pass/fail determination and expression of results	25
7.10	Hardness of bite registration materials	25
7.10.1	Apparatus	25
7.10.2	Specimen preparation	25
7.10.3	Test procedure	25
7.10.4	Evaluation	26
7.10.5	Pass/fail determination and expression of results	26
	Annex A (normative) Figures	27
	Annex B (normative) Standardized hand mixing methods	35
	Bibliography	38