

STN	Stomatológia Elektrické škrabky (ISO 18397: 2025)	STN EN ISO 18397 85 6013
------------	--	--

Dentistry - Powered scaler (ISO 18397:2025)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/25

Obsahuje: EN ISO 18397:2025, ISO 18397:2025

Oznámením tejto normy sa ruší
STN EN ISO 18397 (85 6013) z júla 2016

141099

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2025
Slovenská technická norma a technická normalizačná informácia je chránená zákonom č. 60/2018 Z. z. o technickej normalizácii
v znení neskorších predpisov.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 18397

July 2025

ICS 11.060.25

Supersedes EN ISO 18397:2016

English Version

Dentistry - Powered scaler (ISO 18397:2025)

Médecine bucco-dentaire - Instruments pour
détartrage (ISO 18397:2025)

Zahnheilkunde - Angetriebener Scaler (ISO
18397:2025)

This European Standard was approved by CEN on 3 June 2025.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN ISO 18397:2025 (E)

Contents	Page
European foreword.....	3

European foreword

This document (EN ISO 18397:2025) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2026, and conflicting national standards shall be withdrawn at the latest by January 2026.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 18397:2016.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 18397:2025 has been approved by CEN as EN ISO 18397:2025 without any modification.



International Standard

ISO 18397

Dentistry — Powered scalers

Médecine bucco-dentaire — Instruments pour détartrage

**Second edition
2025-07**

ISO 18397:2025(en)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

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
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

ISO 18397:2025(en)**Contents**

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Classification of scaler handpieces	3
5 Requirements and performance	3
5.1 General	3
5.2 Materials	3
5.3 Drop test	4
5.4 Noise level	4
5.5 Surfaces	4
5.6 Electrical power supply	4
5.7 Energy for light source	4
5.8 Air supply	4
5.9 Supply of cooling liquid	4
5.10 Air and water pressure	4
5.11 Temperature	5
5.11.1 Temperature rise of housing	5
5.11.2 Temperature, excessive	5
5.12 Vibrations	5
5.13 Resistance to reprocessing	5
5.14 Leakage and/or ingress of water	5
5.15 Electromagnetic compatibility	5
5.16 Operating controls	5
5.17 Usability	6
5.18 Connection	6
5.18.1 General	6
5.18.2 Connections for air-powered scaler handpieces	6
5.18.3 Connector for electrical-powered scaler handpieces	6
5.19 Scaler tip performance	6
5.19.1 Scaler tip connection	6
5.19.2 Extraction force	6
5.19.3 Holding torque	6
5.19.4 Insertion force	7
5.19.5 Tightening torque	7
5.19.6 Stall effort	7
5.19.7 Output power of powered scaler	7
5.19.8 Breakage resistance	7
5.20 Frequency	7
5.21 Amplitude	7
6 Sampling	7
7 Measurement and test method	8
7.1 General test conditions	8
7.2 Visual inspection	8
7.3 Electrical power supply	8
7.4 Air supply	8
7.4.1 Apparatus	8
7.4.2 Procedure	8
7.5 Supply of cooling liquid	8
7.5.1 Apparatus	8
7.5.2 Procedure	8

ISO 18397:2025(en)

7.6	Air and water pressure	8
7.6.1	Apparatus	8
7.6.2	Procedure	8
7.7	Measuring device for dimensions	9
7.8	Scaler tips	9
7.8.1	Extraction force	9
7.8.2	Holding torque	9
7.8.3	Insertion force	9
7.8.4	Tightening torque	9
7.8.5	Stall effort	10
7.8.6	Output power of powered scaler	10
7.8.7	Breakage resistance	12
7.9	Frequency	12
7.9.1	Apparatus	12
7.9.2	Procedure	12
7.10	Amplitude	13
7.10.1	Apparatus	13
7.10.2	Procedure	13
7.11	Noise level	14
7.11.1	Apparatus	14
7.11.2	Test conditions	14
7.11.3	Procedure	14
7.12	Rise of housing temperature	14
7.13	Excessive temperature	14
7.14	Resistance to reprocessing	14
8	Instructions for use, maintenance and service	14
9	Technical description	15
10	Marking	16
10.1	General	16
10.2	Scaler handpieces	16
10.3	Scaler tips	16
11	Labelling	17
12	Packaging	17
Annex A	(informative) Calculation example for output power	18

ISO 18397:2025(en)**Foreword**

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 18397:2016), which has been technically revised.

The main changes are as follows:

- adaption of the part designations for the scaler tips;
- reducing the maximum frequency of the scaler tips for air-powered scaler handpieces;
- new specification on when to provide information on output power in the instructions for use;
- simplification of the description for the amplitude limit value.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

ISO 18397:2025(en)**Introduction**

Scaler handpieces and scaler tips have been used in dental treatment procedures for many years.

As technical development has resulted in improved scaler handpieces and tips, this document is necessary to ensure the level of safety and performance, both of the individual devices and in combination, is at an appropriate level.

Dentistry — Powered scalers

1 Scope

This document specifies the requirements and test methods for air-powered and electrical-powered scaler handpieces and scaler tips, including piezo and magnetostrictive type ultrasonic scalers, operated as stand-alone items or connected to dental units, for use on patients. This document also contains specifications on manufacturers' instructions, marking and packaging.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 5349-1, *Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 1: General requirements*

ISO 5349-2, *Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 2: Practical guidance for measurement at the workplace*

ISO 7494-1, *Dentistry — Stationary dental units and dental patient chairs — Part 1: General requirements*

ISO 9168, *Dentistry — Hose connectors for air driven dental handpieces*

ISO 9687, *Dentistry — Graphical symbols for dental equipment*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14457, *Dentistry — Handpieces and motors*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 21531, *Dentistry — Graphical symbols for dental instruments*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 61672-1, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 80601-2-60, *Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN