

SLOVENSKI STANDARD oSIST prEN ISO 18397:2015

01-januar-2015

Zobozdravstvo - Pripomočki za čiščenje (Scaler) (ISO/DIS 18397:2014)

Dentistry - Powered scaler (ISO/DIS 18397:2014)

Zahnheilkunde - Zahnreiniger (Scaler) und dazugehörige Spitzen (ISO/DIS 18397:2014)

Médecine bucco-dentaire - Instruments pour le détartrage (ISO/DIS 18397:2014)

Ta slovenski standard je istoveten z: prEN ISO 18397 rev

ICS:

https://discounterprinter.azobotehnični instrumentii 113a-Dental instruments/514b6b94/sist-en-iso-18397-2016

oSIST prEN ISO 18397:2015 en,fr,de

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 18397:2016

DRAFT INTERNATIONAL STANDARD ISO/DIS 18397

ISO/TC **106**/SC **4** Secretariat: **DIN**

Voting begins on:

Voting terminates on:

2014-09-18 2015-02-18

Dentistry — Powered scaler

Médecine bucco-dentaire — Scalers

ICS: 11.060.25

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 18397:2016

https://standards.iteh.ai/catalog/standards/sist/fd75113a-22e1-42fd-90a3-b19c514b6b94/sist-en-iso-18397-2016

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.



Reference number ISO/DIS 18397:2014(E)

iTeh Standards (https://standards.iteh.ai) Document Preview

<u> 5151 EN 150 1839/:2016</u>

https://standards.iteh.ai/catalog/standards/sist/fd75113a-22e1-42fd-90a3-b19c514b6b94/sist-en-iso-18397-2010

Copyright notice

This ISO document is a Draft International Standard and is copyright-protected by ISO. Except as permitted under the applicable laws of the user's country, neither this ISO draft nor any extract from it may be reproduced, stored in a retrieval system or transmitted in any form or by any means, electronic, photocopying, recording or otherwise, without prior written permission being secured.

Requests for permission to reproduce should be addressed to either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office Case postale 56 • CH-1211 Geneva 20 Tel. + 41 22 749 01 11 Fax + 41 22 749 09 47 E-mail copyright@iso.org Web www.iso.org

Reproduction may be subject to royalty payments or a licensing agreement.

Violators may be prosecuted.

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 18397:2016

Cor	itents	S	Page
Fore	word		vi
Intro	duction	1	vii
1	Scone	3	1
2	-	native references	
3		s and definitions	
4	Class	ification of scaler handpieces	3
5	Requirements and performance		3
	5.1	General	3
	5.2	Materials	3
	5.3	Drop test	3
	5.4	Noise level	3
	5.5	Surfaces	3
	5.6	Electrical power supply (if applicable)	3
	5.7	Energy for light source (if applicable)	4
	5.8	Air supply	4
	5.9	Supply of cooling liquid	
	5.10	Air and water pressure	4
	5.11	Temperature	4
	5.12	Vibrations	
	5.13	Resistance to reprocessing	4
	5.14	Leakage and/or ingress of water	5
	5.15	Electromagnetic compatibility	5
	5.16	Operating controls Usability	5
	5.17	Usability	5
	5.18	Connection	
	5.19	Scaler tip	6
	5.20	Frequency	6
	5.21	Amplitude	7
6	Samp	SIST EN ISO 18397:2016 ards.iteh.ai/catalog/standards/sist/fd//5113a-22e1-42fd-90a3-b19c514b6b94/sist-e	7
https 7	://stand	ards.iteh.ai/catalog/standards/sist/fd75113a-22e1-42fd-90a3-b19e514b6b94/sist-e ng	en-iso-18397-20
,	7.1	General test conditions	
	7.1	Visual inspection	
	7.2	Power supply - Electrical	
	7.3 7.4	Air supply	
	7. 1 7.5	Supply of cooling liquid	
	7.6	Air and water pressure	
	7.7	Measuring device for dimensions	
	7.8	Scaler tips	
	7.0 7.9	Frequency	
	7.10	Amplitude	
	7.10	Noise level	
	7.12	Temperature rise of housing	
	7.12	Temperature, excessive	
	7.14	Resistance to reprocessing	
8	Instr	uctions for use, maintenance and service	
9		nical description	
		-	
10	10.1	ing General	
	10.1		
		Scalar tips	14 15

ISO/DIS 18397:2014(E)

11	Labelling	.15
12	Packaging	.15
Annex	x A (informative) Calculation example for power output	.16
Biblio	graphy	.17

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 18397:2016

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 18397 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This second/third/... edition cancels and replaces the first/second/... edition (ISO 15606:1999, ISO 22374:2005), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

This International Standard is the combination of the following two ISO standards in one.

ISO 15606:1999, Dental handpieces — Air powered scalers and scaler tips

ISO 22374:2005, Dentistry — Dental handpieces — Electrical powered scalers and scaler tips

SIST EN ISO 18397:2016

https://ctandards.iteh.gi/catalog/ctandards/sist/fd75113g_22e1_42fd_90g3_h19c514h6h94/sist_en_iso_18397_201

Introduction

Dental 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 revised standard is necessary to ensure the level of safety and performance, both of the individual devices and in combination, is at an appropriate level.

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 18397:2016

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 18397:2016