Dear Member,

The following document is being circulated for vote at CENELEC level :

Work Item Number	:	62932
CLC reference	:	prEN IEC 62304:2021
Reference document	:	IEC 62304:202X (62A/1422/CDV) (EQV)
Title	:	Health software - Software life cycle processes
Technical Body	:	CLC/TC 62
IEC/TC	:	IEC/SC 62A
Procedure	:	Parallel Vote on CDV
BT decision	:	-
Submission date	:	2021-01-08
Deadline	:	2021-03-26
doa	:	dor + 3 months
dop	:	dor + 9 months
dow	:	dor + 36 months
Directive(s)	:	-
Mandate(s)	:	-
Supersedes	:	EN 62304:2006/corrigendum Nov. 2008 EN 62304:2006 + A1:2015
Available languages	:	-
Document link	:	-
(Acting) Secretary	:	Mr Petar Luzajic
Assistant Secretary	:	-
Chairman/Convenor	:	Dr Peter Linders
Permanent Delegate	:	-
c.c	:	Mr Vaughan, Mr Russell
CCMC comment	:	-

CCMC general remarks :

- The National Committees are invited to check carefully the validity of the proposed implementation dates and Directive(s).
- Superseded documents are withdrawn at the dow of the new EN/HD or at the publication date of the new TS/TR.
- If the above project is submitted simultaneously to the IEC voting procedure in the framework of the IEC/CENELEC co-operation agreement (parallel procedure) you will receive the text of the document from the IEC Central Office. Should your vote be different in IEC and CENELEC, a detailed technical justification shall be sent to the CCMC, with copy to the IEC Central Office.
- If the above project is an amendment circulated to withdraw special national conditions and/or A-deviations from a standard the National Committees are invited to check their national situation regarding the same standard and to inform the CCMC of any change, with a copy to the Secretary of the relevant Technical Body. There is no possibility to vote through the usual online voting system.

Yours sincerely,

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62A/1422/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 62304 ED2	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2021-01-01	**2021-03-26**
SUPERSEDES DOCUMENTS:	
62A/1349/CDV, 62A/1383B/RVC	

IEC SC 62A : COMMON ASPECTS OF ELECTRICAL EQUIPMENT USED IN MEDICAL PRACTICE	
SECRETARIAT: United States of America	SECRETARY: Ms Hae Choe
OF INTEREST TO THE FOLLOWING COMMITTEES: TC 62,SC 62B,SC 62C,SC 62D,TC 65,TC 66,TC 76,TC 106,TC 108	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING **Attention IEC-CENELEC parallel voting** The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

IEC 62304 Ed. 2: Health software - Software life cycle processes

PROPOSED STABILITY DATE: 2024

NOTE FROM TC/SC OFFICERS:

Please note that this draft is a joint project between IEC/SC 62A and ISO/TC 215 and is IEC led. During the last CDV stage, this project was approved on the IEC side but not approved in ISO and CENELEC. A task group was assigned to develop proposed resolutions to the comments and to the draft which were reviewed by the 62304 Project Team and the IEC/ISO Joint Working Group. Attached is the result of that extensive work. Some comments did not offer specific changes but provided ideas that may be better utilized during the next maintenance cycle for this document.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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HEALTH SOFTWARE –

SOFTWARE LIFE CYCLE PROCESSES

FOREWORD

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International Standard IEC 62304 has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice,in cooperation with ISO Technical Committee 215, Health informatics. Table C.5 was prepared by ISO/IEC JTC 1/SC 7, Software and systems engineering.

It is published as a dual logo standard.

This second edition cancels and replaces the first edition published in 2006 and Amendment 1:2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) the scope of this document has been expanded to HEALTH SOFTWARE;