

Standards on Medical Devices

Laboratorio di Tecnologie Biomediche A.A. 2017/2018

PhD Student Licia Di Pietro

dipietrolicia@gmail.com

What is a standard? (1/2)

European Directive 98/34/CE 1998 :

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0034&from=en>

‘**standard**’, a technical specification approved by a recognised standardisation body for repeated or continuous application, with which compliance is not compulsory and which is one of the following:

- **international standard**: a standard adopted by an international standardisation organisation and made available to the public,
- **European standard**: a standard adopted by a European standardisation body and made available to the public,
- **national standard**: a standard adopted by a national standardisation body and made available to the public;

What is a standard? (2/2)

Principal characteristics of Standards:

- are **volunteers**;
- are based on the **consensus** and on the **transparency**;
- are re-examined every **5 years**;
- are made by **standardization bodies**.

Some standards have regulatory effect

- Harmonised standards in EU
- Recommended standards in USA

Where do standards come from?

There are particular institutions, national and international, all non-profit, which constantly develop and update this regulatory activity.



- **UNI** – Ente Nazionale Italiano di Unificazione
- **CEN** – Comité Européen de Normalisation
- **ISO** – International Organization of Standardization
- **IEC** – International Electrotechnical Commission
- **CENELEC** – Comité Européen de Normalisation Électrotechnique
- **CEI** – Comitato Elettrotecnico Italiano

Who are ISO and IEC?

- The **International Organization for Standardization** (ISO) is a worldwide federation of national standards bodies.
- The **International Electrotechnical Commission** (IEC) is the world's leading organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

The official purpose for the issuance of ISO/IEC Standards is to facilitate world trade through standardization



INTERNATIONAL
ELECTROTECHNICAL
COMMISSION



International
Organization for
Standardization

Standardization bodies (1/2)



Standardization bodies (2/2)



Standards and Medical Devices (1/2)

- **Device lifecycle is regulated by:**
 - ISO 13485 for Quality System
 - ISO 14971 for Risk Management
 - ISO 14155 and various guidelines for Clinical Investigations
- **Each product category is than regulated by technical norms**
 - For electro medical devices IEC 60601-1
 - For sterile device ISO 11137 et al
 - For devices in contact with the body ISO 10993
 - Multiple harmonised and not harmonised norms for technical regulation of product-specific features

Standards and Medical Devices (2/2)

IEC standards have numbers in the range 60000–79999



The IEC cooperates closely with the International Organization for Standardization (ISO)



Other standards developed in cooperation between IEC and ISO are assigned numbers in the 80000 series

IEC 60601 example (1/4)

IEC 60601 Medical Electrical Equipment

IEC 60601-x-xx

- The IEC 60601-1-xx series of **collateral** standards for MEDICAL DEVICE ELECTRICAL EQUIPEMENT
- The IEC 60601-2-xx series od **particular** standards for particular types of MEDICAL ELECTRICAL EQUIPMENT
- The IEC 60601-3-xx series of **performance** standards for particular types of MEDICAL ELECTRICAL EQUIPEMNT

IEC 60601 example (2/4)

Collateral Standards

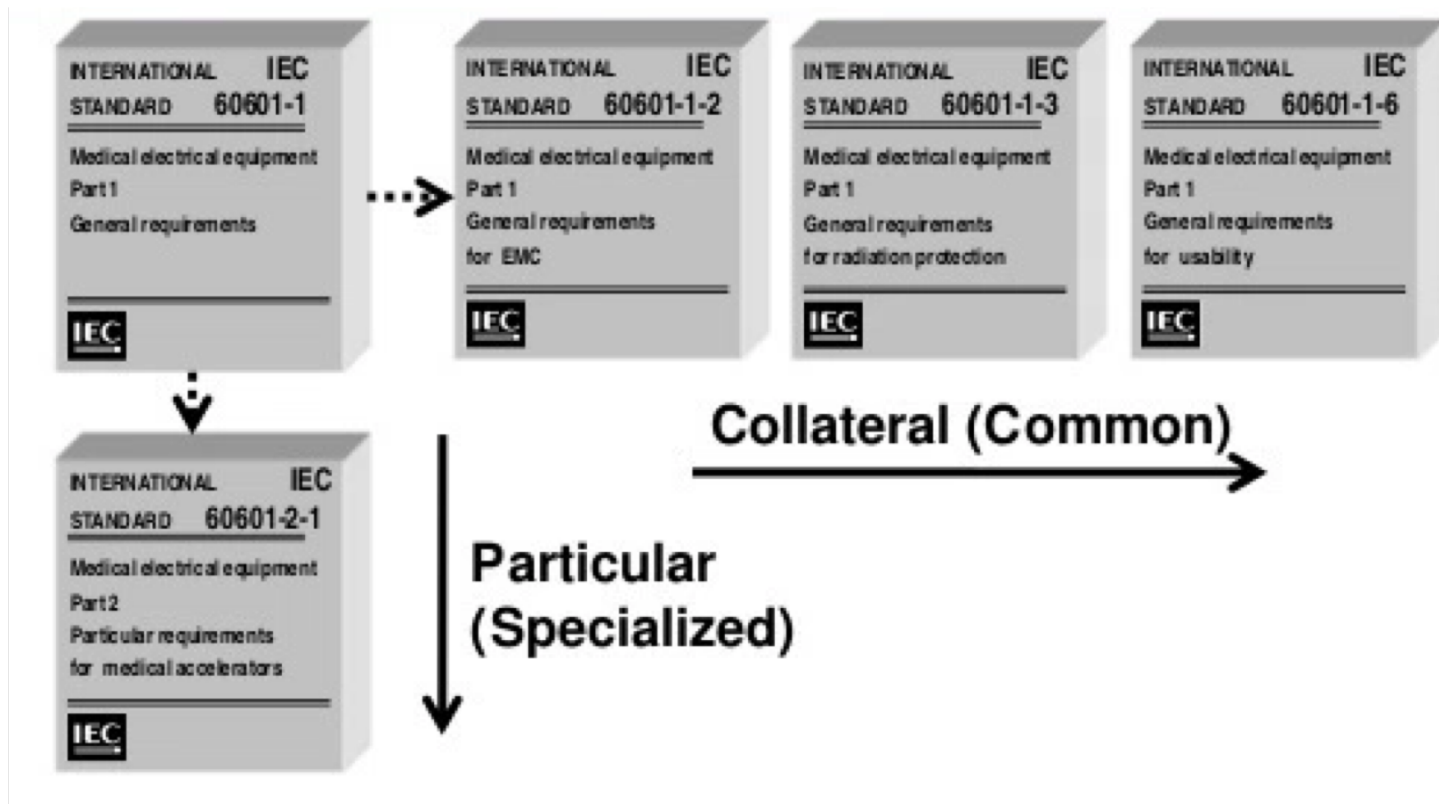
- IEC 60601-1-2, Medical electrical equipment – *Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests*
- IEC 60601-1-3, Medical electrical equipment – *Part 1-3: General requirements for safety - Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*
- IEC 60601-1-6, Medical electrical equipment – *Part 1-6: General requirements for safety - Collateral standard: Usability*

IEC 60601 example (3/4)

Particular Standards

- IEC 60601-2-1 Medical electrical equipment - *Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*
- IEC 60601-2-2, Medical electrical equipment - *Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*
- IEC 60601-2-4, Medical electrical equipment - *Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*

IEC 60601 example (4/4)



EN - How to download a standard? (1/5)



UNIVERSITÀ DI PISA

Sistema Bibliotecario d'Ateneo

- EN

A (14) B (7) C (8) D (5) E (8) F (2) G (3) H (1) I (13) J (2) K (2) L (8) M (4) N (3) O (4) P (8) R (1) S (7) T (8) U (3) V (1) W (2)

Titolo	Info	Ambiti disciplinari	Condizioni di accesso
Normattiva		Diritto	FREE
Norme tecniche CFI		Economia Fisica Informatica Ingegneria Matematica	UNIPI
Norme tecniche EN		Economia Fisica Ingegneria Matematica	UNIPI

English

EN - How to download a standard? (2/5)

User Login

Account: University of Pisa
Account ID: 5990960011
Session: - - -

Returning Registered Users:

If you have previously registered, Please login to your user profile.

Email Address:

User Password*:

Submit

Reset

» [Forgot your password?](#)

* The User Password was created when you first registered. This is different than the password tied to your company account.

New User or Never Registered?

Welcome! Please click the button to register.

Register

Subscribe with you email!

[Privacy](#) | [Legal](#) | [Terms and Conditions](#)

EN - How to download a standard? (3/5)

Main Menu

Welcome, **Licia** [User ID: 3637247]

→ [Not Licia?](#)

→ [Update your profile / Change your password](#)

→ [Subscriber Logout](#)

Account: University of Pisa

Account ID: 5990960011

Session: 716845052

Your IP: 131.114.235.8

Select a Service from your current subscription:

➤ [IHS Engineering Workbench](#)

➤ [Support and Training](#)



The IHS Web site, the database services, and other information provided through this Web site are made available to users subject to the Subscriber's compliance without modification of the IHS Internet Terms and Conditions and notices contained herein. By accessing or using this site or the IHS database services, the Subscriber agrees to be bound by the IHS Internet Terms and Conditions and notices.

Access standards and related technical reference information using this single intuitive interface with advanced knowledge discovery and research technologies.

EN - How to download a standard? (4/5)



RESEARCH

Retrieve highly actionable concepts and get answers to your questions.

Refine Source Selection



Save Query / Set Alert

Advanced Query Tools

Recent News

Quantifying Untapped Natural Gas Resources

A non-invasive method can help natural gas producers better understand shale samples and inform...

Smart Safe Protects Valuables Remotely

The smart safe keeps anything from money, passports, medicine and jewelry safe. Users can access...

Study Suggests That Basic Password Guidance Can Improve Account Security

A study concerning account passwords suggests that better guidance and detailed support will

Recent Searches

- DS DS/EN ISO 80601-2-69 - Med...
- BSI BS ISO 11712 - Anaesthetic a...
- DS DS/ISO 11712 - Anaesthetic a...
- ISO 11712 - Anaesthetic and respl...
- DS DS/EN ISO 14971 - Medical d...
- ISO 14971 - Medical devices - Ap...
- 7000

Recent Bookmarks

There are no bookmarks.

Recent Documents

- DANSK DS/EN ISO 80601-2-69 - ...
- BSI BS ISO 11712 - Anaesthetic a...
- DS DS/ISO 11712 - Anaesthetic a...
- DANSK DS/EN ISO 5384 - Anaes...
- ISO 11712 - Anaesthetic and respl...
- DS DS/EN ISO 14971 - Medical d...
- ISO 14971 - Medical devices - Ap...

Recent Projects

There are no projects.

My Watch Lists

There are no watch lists.

EN - How to download a standard? (5/5)

Document Viewer Version 2.51 **DANSK DS/EN ISO 80601-2-69 - Medical electrical equipment - Part 2-69: Particular ...** Close

DOCUMENT SUMMARY DOCUMENT HISTORY RELATED DOCUMENTS

DANSK DS/EN ISO 80601-2-69 - M... <<
By Dansk Standard

► Document Notes (0)

► Table of Contents

🔍 ⌵ ⌶ 100% ↺ ↻ ⌵ ⌶ 1 / 62 💬 📌 👁️ ⬇️

 Dansk standard **DS/EN ISO 80601-2-69**
1. udgave
2014-09-22

**Elektromedicinsk udstyr –
Del 2-69: Særlige krav til grundliggende
sikkerhed og væsentlige funktions-
egenskaber for udstyr til oxygen-
koncentratorer**

Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance

CEI - How to download a standard? (1/8)



UNIVERSITÀ DI PISA

Sistema Bibliotecario d'Ateneo

- CEI

A (14) B (7) C (8) D (5) E (8) F (2) G (3) H (1) I (13) J (2) K (2) L (8) M (4) N (3) O (4) P (8) R (1) S (7) T (8) U (3) V (1) W (2)

Titolo	Info	Ambiti disciplinari	Condizioni di accesso
Normattiva		Diritto	FREE
Norme tecniche CEI		Economia Fisica Informatica Ingegneria Matematica	UNIPI
Norme tecniche EN		Economia Fisica Ingegneria Matematica	UNIPI

English

CEI - How to download a standard? (2/8)

The screenshot shows the SAI GLOBAL platform interface. At the top left is the logo 'SAI GLOBAL' with a globe icon and 'platform' text. To the right is the text 'Free Directory'. Further right are login fields for 'Email' and 'Password', a 'Log In' button, and links for 'Keep me logged in' and 'Forgotten your password?'. Below the header is a navigation menu with 'Home', 'Search', 'Register', 'About', 'Help', and 'Fair Use Policy'. The main content area features a 'Quick Search (by Doc. Number)' section with a plus icon and an 'Advanced Search' section with a minus icon. The 'Advanced Search' section contains a 'Search' tab and three input fields: 'Doc. Number' (with a hint: 'Enter your document number (or part of) here: e.g. 'ISO9001' or 'API 650' or 'API MPM CH17.1)'), 'Title' (with a hint: 'Enter your document title (or part of) here: e.g. 'BOILER PRESSURE VESSEL' or 'PART 1)'), and 'Keywords' (with a hint: 'Enter keywords to search within the bibliographic entry'). There is also a 'Current' checkbox with the text 'Tick this box to exclude historic documents (i.e. cancelled and superseded)'. At the bottom of the search form are 'Search' and 'Clear' buttons.

» The smart way to manage your information

Please feel free to browse our on-line database.

You are currently accessing the system as a GUEST user. Therefore access will be restricted to searching and viewing a summary of our full bibliographic data.

If you (or your company) have an active subscription, please log in using your company email address. If this is the first time you have logged in then you will need to register yourself within the system first. Please use the **Login** page to log in or to register yourself.

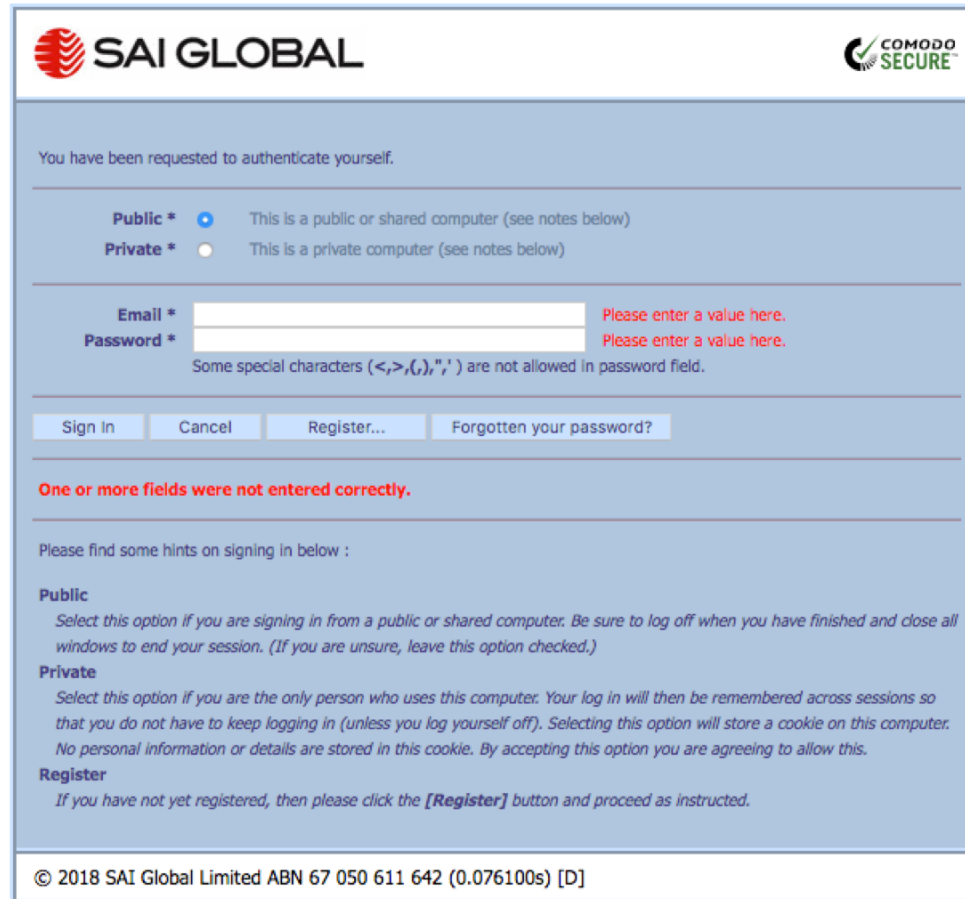
» Global standards management is changing ... and we are leading the way, let us show you how!

To access the full system and all of its advanced features you must have an active subscription in place.

Subscription benefits include:

- Customisable solution that works with your business
- Seamless integration across departments and locations
- Delivery of relevant information when and how you need it
- Assists with ISO 9001 compliance or equivalent
- Automate manual processes
- Intelligent search capabilities
- Flexible admin tools provide on-demand usage reports, user management functions, alerts and more

CEI - How to download a standard? (3/8)



The screenshot shows the SAI Global login interface. At the top left is the SAI GLOBAL logo, and at the top right is the COMODO SECURE logo. Below the logos, a message states: "You have been requested to authenticate yourself." The form contains two radio buttons for "Public" (selected) and "Private". Below these are input fields for "Email" and "Password", both with red error messages: "Please enter a value here." A note below the password field states: "Some special characters (<, >, (,), ') are not allowed in password field." At the bottom of the form are buttons for "Sign In", "Cancel", "Register...", and "Forgotten your password?". A red error message reads: "One or more fields were not entered correctly." Below the form, there are instructions for "Public", "Private", and "Register" options. At the very bottom, the copyright notice reads: "© 2018 SAI Global Limited ABN 67 050 611 642 (0.076100s) [D]"

SAI GLOBAL **COMODO SECURE**

You have been requested to authenticate yourself.

Public * This is a public or shared computer (see notes below)
Private * This is a private computer (see notes below)

Email * Please enter a value here.
Password * Please enter a value here.
Some special characters (<, >, (,), ') are not allowed in password field.

[Sign In](#) [Cancel](#) [Register...](#) [Forgotten your password?](#)

One or more fields were not entered correctly.

Please find some hints on signing in below :

Public
Select this option if you are signing in from a public or shared computer. Be sure to log off when you have finished and close all windows to end your session. (If you are unsure, leave this option checked.)


Private
Select this option if you are the only person who uses this computer. Your log in will then be remembered across sessions so that you do not have to keep logging in (unless you log yourself off). Selecting this option will store a cookie on this computer. No personal information or details are stored in this cookie. By accepting this option you are agreeing to allow this.

Register
If you have not yet registered, then please click the **[Register]** button and proceed as instructed.

© 2018 SAI Global Limited ABN 67 050 611 642 (0.076100s) [D]

CEI - How to download a standard? (4/8)



Please complete the registration form below.

Email *

Password *

Confirm

Some special characters (<, >, (,), ', ') are not allowed in password field.

© 2018 SAI Global Limited ABN 67 050 611 642 (0.074100s) [D]

CEI - How to download a standard? (5/8)

SAI GLOBAL **COMODO SECURE™**

Please complete the registration form below.

Email

Password

Title

First Name *

Last Name

Company

Business Unit

Department

Country *



Tel.

Mobile

Confirm *

© 2018 SAI Global Limited ABN 67 050 611 642 (0.089600s) [D]

CEI - How to download a standard? (6/8)



Confirm your registration – Further Action Required

Your Privacy Matters to us!

For your security, a confirmation email has been sent to your email address.

To **activate your account** and use your new credentials, you will need to access your email and confirm your identity, by following the instructions in the email.

Note:
If you do not receive the confirmation message within a few minutes of registering, please check your **Junk E-mail folder** just in case the confirmation email was delivered there instead of your inbox.


For continued security, you will be asked to reconfirm your identity on a regular basis to reduce any misuse of your account.


© 2018 SAI Global Limited ABN 67 050 611 642 (0.088200s) [D]

CEI - How to download a standard? (7/8)




- Home
- Cerca**
- Il mio conto
- Informazioni su
- Guida
- Fair Use Policy

Ricerca rapida (per numero di documento) 

Ricerca Avanzata 

Norme	Codice ICS	Ultime	Raccolte
Numero Norma	<input type="text" value="60601-1"/>		
Titolo	<input type="text" value="Inserire qui il titolo del documento o parte di esso: per esempio 'BOILER PRESSURE VESSEL' or 'PART 1'"/>		
Parole Chiave	<input type="text" value="Inserire qui le parola da cercare all'interno delle informazioni bibliografiche"/>		
Ente Normatore	<input type="text"/>	Limitare la ricerca per Ente Normatore	
Paese	<input type="text"/>	Limitare la ricerca per paese	
Corrente	<input checked="" type="checkbox"/> Deseleziona per includere documenti storici (cioè annullati e/o sostituiti)		

[Hai bisogno di altre opzioni di ricerca?](#)

Le Mie Ricerche Salvate (2) 

CEI - How to download a standard? (8/8)

The screenshot shows the SAI GLOBAL platform interface. At the top, there are logos for SAI GLOBAL, the CEI platform, and the Italian Republic emblem. A navigation menu on the left includes Home, Cerca (highlighted), Il mio conto, Informazioni su, Guida, and Fair Use Policy. The main search area shows a search for 'Numero Norma: 60601-1 Corrente: SI'. Below this, there are sections for 'Le Mie Ricerche Salvate (2)', 'Campi da esportare', and a list of search results. The results list four CEI standards with their titles, combined languages, and latest versions.

SAI GLOBAL platform

Home
Cerca
Il mio conto
Informazioni su
Guida
Fair Use Policy

Ricerca rapida (per numero di documento) +
Ricerca Avanzata -

Hai cercato: Numero Norma: **60601-1** Corrente: **SI**
Modificare i suoi criteri di ricerca Cancella

Le Mie Ricerche Salvate (2) +

Campi da esportare +

Esporta Mostra risultati con testo completo Ordina i risultati per Rilevanza

[#] Pagina 1 su 25 : 368 risultati

- CEI EN 60601-1** Latest Version: 2007 AMD 12 2015
APPARECCHI ELETTROMEDICALI - PARTE 1: PRESCRIZIONI GENERALI RELATIVE ALLA SICUREZZA FONDAMENTALE E ALLE PRESTAZIONI ESSENZIALI
COMBINED: ENGLISH/ITALIAN
Uno o più documenti disponibili per il download
- CEI EN 60601-1-1** Latest Version: 2ED 2003
APPARECCHI ELETTROMEDICALI - PARTE 1: NORME GENERALI PER LA SICUREZZA - NORMA COLLATERALE: PRESCRIZIONI DI SICUREZZA PER I SISTEMI ELETTROMEDICALI
COMBINED: ENGLISH/ITALIAN
Uno o più documenti disponibili per il download
- CEI EN 60601-1-2** Latest Version: 4ED 2016
APPARECCHI ELETTROMEDICALI - PARTE 1-2: PRESCRIZIONI GENERALI RELATIVE ALLA SICUREZZA FONDAMENTALE E ALLE PRESTAZIONI ESSENZIALI - NORMA COLLATERALE: COMPATIBILITÀ ELETTROMAGNETICA - PRESCRIZIONI E PROVE
ENGLISH, ITALIAN
Uno o più documenti disponibili per il download
- CEI EN 60601-1-3** Latest Version: 2009 AMD 11 2017
APPARECCHI ELETTROMEDICALI - PARTE 1-3: PRESCRIZIONI GENERALI PER LA SICUREZZA E PRESTAZIONI ESSENZIALI - NORMA COLLATERALE: PRESCRIZIONI GENERALI PER LA RADIOPROTEZIONE IN APPARECCHI RADIOLOGICI PER DIAGNOSTICA
COMBINED: ENGLISH/ITALIAN
Uno o più documenti disponibili per il download