American National Standard

ANSI/AAMI/ST81:2004/(R)2016

Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices

AAMI
Advancing Safety in Healthcare Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific need of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices

Approved 2 December 2004 by
Association for the Advancement of Medical Instrumentation

Approved 13 December 2004 and reaffirmed 24 March 2010 and 23 May 2016 by
American National Standards Institute, Inc.

Abstract: This standard specifies the information to be provided by the medical device manufacturer on the processing of medical devices claimed to be resterilizable and medical devices intended to be sterilized by the processor. Requirements are specified for the information to be provided by the medical device manufacturer so that the medical device can be processed safely and will continue to meet its performance specification. This standard also includes definitions, a bibliography, and informative annexes.

Keywords: cleaning, disinfection, labeling, packaging, sterilization

AAMI Standard

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Glossary of equivalent standards

International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (Note: Documents are sorted by international designation.)

Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:200x[1]	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical

[1] Currently at FDIS stage

International designation	U.S. designation	Equivalency
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
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ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000 and A1:2004	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Instructions for Reusable Device Reprocessing Working Group

This standard was developed by the AAMI Instructions for Reusable Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval.

At the time this standard was published, the **AAMI Instructions for Reusable Device Reprocessing Working Group** had the following members:

Cochairs:
Nancy Chobin, RN, CSPDM
Sandra A. Lee, RN

Members:
Michelle J. Alfa, PhD, FCCM, St. Boniface General Hospital, Winnipeg, Manitoba, Canada
Shelley Allen, AppTec Laboratory Services
Chris B. Anderson, St. Jude Medical Inc.
Lisa Baryschpolec, Ethicon Inc./Johnson & Johnson
Carl W. Bruch, PhD, Hudson, WI
Virginia C. Chamberlain, PhD, Hendersonville, NC
Nancy Chobin, RN, CSPDM, St. Barnabas Healthcare System, Lebanon, NJ
Anne M. Cofiell, CRCST, International Association of Healthcare Central Service Materiel Management
Jacqueline Daley, Sinai Hospital of Baltimore
Anthony J. DeMarinis, MS, CQA, CQM, Davol Inc./CR Bard
Michele Dawn DeMeo, Holy Name Hospital, Teaneck, NJ
Sue Ellen Erickson, MS, CNOR, Newark Beth Israel Medical Center, Cranford, NJ
LeRoy J. Fischbach, Minntech Corporation
France Frechette, MSc, TSO_3 Inc.
Gregory G. Ginsberg, MD, American Society for Gastrointestinal Endoscopy
Zory R. Glaser, PhD, MPH, CSPDM, Johns Hopkins University School of Public Health
Steve N. Goldstine, PhD, DDS, Albuquerque, NM
Wayne D. Grinthal, Olympus America Inc.
Douglas F. Harbrecht, Boston Scientific Corporation
Ronald J. Haselhorst, Cardinal Health
Stephen M. Kovach, Healthmark Industries
Colleen Patricia Landers, RN, Canadian Standards Association
Sandra A. Lee, RN, STERIS Corporation
Chiu Lin, PhD, U.S. Food and Drug Administration
Teckla A. Maresca, LPN, CSPDM, St. Clare's Health System, Denville, NJ
Patrick J. McCormick, Bausch & Lomb Inc.
Russell D. Mills, Zimmer Inc.
Emily Mitzel, MS, Alcon Laboratories Inc.
David Parent, NAMSA
Leslie Phillips, STS duoTEK
Janet Prust, 3M Health Care
Timothy Ramsey, Northview Biosciences
Margaret Reichert, RN, MA, Middleburg Heights, OH
Linda Slone, RN, CNOR, Sibley Memorial Hospital, Washington, DC
Eugenia Stern, MBA, MS, Alcon Laboratories Inc.
David B. Vogel, Smith & Nephew, Inc.
Nora Wikander, RN, CSPDM, St. Joseph's Wayne Hospital, Wayne, NJ
Christine H. Yunker, Abbott Laboratories

Alternates:
Solomon Alade, PhD, Alcon Laboratories Inc.
Ralph J. Basile, MBA, Healthmark Industries
Richard H. Bean, Zimmer Inc.
John Broad, NAMSA
Trabue D. Bryans, AppTec Laboratory Services
Anne Burke, TSO_3 Inc.
Carlos Chavez, PhD, Abbott Laboratories
Charles Cogdill, Boston Scientific Corporation
Kimbrell Darnell, CR Bard

Thomas J. Frazar, DePuy/Johnson & Johnson
Jim Kaiser, Bausch & Lomb Inc.
Susan G. Klacik, International Association of Healthcare Central Service Materiel Management
Martha T. O'Lone, U.S. Food and Drug Administration
Sarah Toole, RM, Nelson Laboratories Inc.
David Tucholski, Cardinal Health
John W. Walker, STERIS Corporation
Martha Young, 3M Health Care

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

AAMI Sterilization Standards Committee

Cochairs:
Victoria Hitchins, PhD
William E. Young

Members:
Trabue D. Bryans, Apptec Laboratory Services
Virginia C. Chamberlain, PhD, Hendersonville, NC
Nancy Chobin, RN, CSPDM, St. Barnabas Health Care System, Lebanon, NJ
Anne M. Cofiell, CRCST, International Association of Healthcare Central Service Materiel Management
Charles Cogdill, Boston Scientific Corporation
Ramona Connor, Association of periOperative Registered Nurses
Kimbrell Darnell, CR Bard
Georgia P. Dash, RN, MS, CIC, Association for Professionals in Infection Control and Epidemiology
Lisa Foster, Sterigenics International
James M. Gibson, Jr., JM Gibson Associates
Barbara J. Goodman, RN, CNOR, Rising Sun, MD
Joel R. Gorski, PhD, NAMSA
Susan Hadfield, Canadian Standards Association
Deborah A. Havlik, Hospira, Inc.
Victoria Hitchins, PhD, U.S. Food and Drug Administration
Clark W. Houghtling, Cosmed Group Inc.
Richard M. Johnson, MSc, Abbott Laboratories
Lois Atkinson Jones, MS, Cary, NC
Byron J. Lambert, PhD, Guidant Corporation
Sandra A. Lee, RN, STERIS Corporation
David Liu, Johnson & Johnson
Jeff Martin, Alcon Laboratories Inc.
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Thomas K. Moore, Getinge USA
Barry F. J. Page, Garner, NC
Phil M. Schneider, 3M Health Care
Michael H. Scholla, MS, PhD, DuPont Nonwovens
Frank Sizemore, American Society for Healthcare Central Service Professionals
Gregory O. Stecklein, MS, MSM, Cardinal Health
William N. Thompson, TYCO Healthcare/Kendall
James Whitbourne, STS duoTEK
James L. Whitby, MA, MB, FRCP, London, Ontario, Canada
Thelma Wilcott, Becton Dickinson & Company
Martell Kress Winters, Nelson Laboratories Inc.
William E. Young, Deer Park, IL

Alternates:
Lloyd Brown, TYCO Healthcare/Kendall
Lina C. Bueno, DuPont Nonwovens
Craig M. Herring, Johnson & Johnson
Jim Kaiser, Bausch & Lomb Inc.
Susan G. Klacik, CCE, International Association of Healthcare Central Service Materiel Management
Colleen Patricia Landers, RN, Canadian Standards Association
Joseph J. Jasica, Alcon Laboratories Inc.
Chiu Li, PhD, U.S. Food and Drug Administration
Lisa N. McDonald, Becton Dickinson & Company
Ralph Makinen, Guidant Corporation
Mary S. Mayo, CR Bard
David Ford McGoldrick, Abbott Laboratories
Jerry R. Nelson, MS, PhD, Nelson Laboratories Inc.
Jeff Peltier, Boston Scientific Corporation
Janet Prust, 3M Health Care
Nancy J. Rakiewicz, STS duoTEK
Ralph Stick, AppTec Laboratory Services
John W. Walker, STERIS Corporation
Valerie Welter, Hospira, Inc.
William T. Young, Sterigenics International

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Foreword

This standard, ANSI/AAMI ST81:2004, reflects adoption by the United States, with national deviations, of EN ISO 17664:2004, *Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices*.

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.

The United States is one of the ISO members that took an active role in the development of EN ISO 17664, which was prepared by the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 198, *Sterilization of health care products*, in accordance with the Agreement on Technical Cooperation between ISO and CEN (Vienna Agreement). The standard is intended to fill a need for guidance on the instructions that medical device manufacturers should provide to health care personnel regarding cleaning, sterilization, and other elements of reprocessing.

U.S. participation in ISO/TC 198 is organized through the U.S. Technical Advisory Group for ISO/TC 198, administered by the Association for the Advancement of Medical Instrumentation (AAMI). The U.S. TAG for ISO/TC 198 supports the guidance provided in EN ISO 17664, with national deviations as noted in Annex D. Annexes A, B, C, and D of ANSI/AAMI ST81:2004 are for information only.

As used within the context of this document, “shall” indicates requirements to be followed strictly in order to conform to the standard; “should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; “may” is used to indicate that a course of action is permissible within the limits of the standard; and “can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the American National Standard, *Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices* (ANSI/AAMI ST81:2004), but it does provide important information about the development and intended use of the document.

Introduction

This standard applies to those medical devices which are intended for multiple use and require processing to take them from their state at the end of one use to the state of being sterile and ready for their subsequent use. Some medical devices supplied nonsterile but intended to be used in a sterile state will also require similar treatment.

Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices

1 Scope

This standard specifies the information to be provided by the medical device manufacturer on the processing of medical devices claimed to be resterilizable and medical devices intended to be sterilized by the processor.

This standard specifies requirements for the information to be provided by the medical device manufacturer, so that the medical device can be processed safely and will continue to meet its performance specification.

Requirements are specified for processing that consists of all or some of the following activities:

— preparation at the point of use;

— preparation, cleaning, disinfection;

— drying;

— inspection, maintenance, and testing;

— packaging;

— sterilization;

— storage.

When providing instructions for these activities, medical device manufacturers are expected to be aware of the training and knowledge of procedures, and of the processing equipment available to the persons likely to be responsible for processing. It is likely that some processing procedures will be generic and well known and will use equipment and consumables conforming to recognized standards. In this case, a reference in the instructions is all that is required. For those medical devices where instructions for use are not required to accompany the medical device (for instance, simple clamps, forceps, retractors, etc.), other means of communicating the information can be used, e.g., user manuals, symbols, or wall charts supplied separately.

This standard excludes textile devices used in patient draping systems or surgical clothing. ANSI/AAMI ST65:2000 contains information on processing textiles.

NOTE—The principles of this standard may be applied when considering the information to be supplied with medical devices which only require disinfection prior to reuse.

2 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

2.1 chemical: Formulation of compounds intended for use in reprocessing.

NOTE—This includes, for example, detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners, sterilants.

2.2 cleaning: Removal of contamination from an item to the extent necessary for further processing or for intended use.

2.3 disinfection: Process used to reduce the number of viable microorganisms on a product to a level previously specified as appropriate for its further handling or use.

2.4 manual cleaning: Cleaning without the use of a washer or washer-disinfector.

2.5 manufacturer: Organization with responsibility for the design, manufacture, packaging, and labeling of a device before it is placed on the market under its own or another name, regardless of whether these operations are carried out by the manufacturer itself or on its behalf by a third party.

2.6 processing: Activity including cleaning, disinfection, and sterilization necessary to prepare a new or used medical device for its intended use.

2.7 processor: Organization with the responsibility for carrying out the actions necessary to prepare a new or used device for its intended use.

2.8 sterilant: Chemical which has properties to destroy microorganisms, including viruses, when used at correct dilution/dose and applied for recommended exposure time.

2.9 sterile: Free from all viable microorganisms.

2.10 sterilization: Validated process used to render a device free from all forms of viable microorganisms.

NOTE—In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item may be expressed in terms of probability. While this probability may be reduced to a very low number, it can never be reduced to zero. (See ISO 11134.) This probability can only be assured for validated processes.

2.11 validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

2.12 verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

2.13 washer-disinfector: Machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical, and veterinary practice.

3 Information to be provided by the medical device manufacturer

3.1 Reprocessing instructions

At least one validated method for reprocessing the medical device shall be specified.

The following information shall be stated where it is critical to the maintenance of the intended function of the medical device and the safety of the user(s) and the patient:

— details of process steps;

— a description of special equipment and/or accessories;

— specification of process parameters and their tolerances.

NOTE—Further information is provided in Annex A.

3.2 Limitations and restrictions on reprocessing

The manufacturer shall determine if processing in accordance with the provided instructions leads to a degree of degradation that will limit the useful life of the medical device. Where such degradation is established, the manufacturer shall provide an indication of the end of the medical device's ability to safely fulfill its intended use.

3.3 Preparation at the point of use prior to processing

Requirements for preparation at the point of use to ensure satisfactory reprocessing of the medical device shall be specified, if applicable.

Where appropriate, at least the following information shall be included:

— the containers for transportation;

— a description of the support systems (for instance, accessories to hold and protect the instrumentation within the container for transportation, if applicable);

— the maximum period of time that may elapse between use and cleaning;

— a description of the precleaning techniques critical to further processing;

— the requirements for wet or dry transportation of items to the decontamination area.