MEDI
SUSTAINABLE HEALTHCARE SOLUTIONS

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03 November 2014

The Chairperson
Portfolio Committee on Health
South African Parliament

RE: ESTABLISHMENT OF A NOVEL MARKET IN SOUTH AFRICA – REMANUFACTURED SINGLE USE DEVICES

Madam Chairperson,

We thank you for the opportunity to introduce ourselves and the novel concept we wish to establish in South Africa. We have watched with interest as the practice of remanufacturing Single Use Devices (or SUDs) has taken root, established itself over the past 15 years and is now experiencing rapid growth in the USA, followed more recently by several European countries and Australia. We have also monitored the contract sterilisation industry likewise. In due course, as the practice has evolved, been proven and improved, we have come to believe it has matured sufficiently and current evidence suggests it is now appropriate for introduction into South Africa.

Remanufacturing of single use devices offers the following advantages:

- Cost reduction:
  - It is possible to replenish stocks of devices at prices between 35% and 50% less than those of the originals.
  - Devices that are reprocessed are diverted from comparatively expensive medical waste disposal.

- Infection control:
  - Devices are remanufactured under stringent, validated sterility conditions.
  - Reprocessing takes place locally, shortly before use and with minimal intermediate handling to assure minimal risk of compromise before use.

- Quality control:
  - Devices are remanufactured by an accredited facility to quality standards even more stringent than those imposed on the OEM, and checked for material patency, form and function.

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- Inventory control:
  - Devices are sourced locally in ratios directly proportional to local usage.
  - Local sourcing ensures speedy access to devices with which to replenish stock levels and simplified logistics.
  - Consignment stock is constantly monitored and replenished in liaison with the institution's supply chain management.

- Environmental care:
  - Diversion of medical waste reduces the burden on South Africa's already overtaxed disposal infrastructure.
  - Remanufacturing provides an environmentally friendly alternative that ensures more sustainable use of finite resources.

- Convenience:
  - Used devices are placed in bins provided by the reprocessor for the purpose and are collected regularly.
  - Remanufactured devices are returned to the consignment of stock held at the user's premises, ready for use.

Historical Background

We believe there are 3 historical narratives that would be useful in understanding our initiative to establish this market in South Africa:

USA

In the US, as in many countries worldwide and, indeed, in South Africa, reprocessing of SUDs was historically being done in an uncontrolled, non-validated, unlegislated, unregulated fashion, often by cash strapped hospitals themselves, but also by various 3rd party organisations.

The practice of reprocessing SUDs for reuse in USA began in hospitals in the late 70s. Approval of the practice of reusing haemodialysers in the early '80s by the US Public Health Service paved the way for the currently burgeoning 3rd Party reprocessing industry. The FDA policy on instrument reuse from 1987 stated that the decision to reuse rested with the hospital and the practitioner. The decision to reuse was to be based on whether the instrument could be adequately cleaned and sterilised, whether it would not be adversely affected in terms of quality (material, form and function), and whether it remained safe and effective for its intended use.

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In a letter issued in 1998, the FDA commented on the absence of evidence of adverse patient outcomes related to the reuse of SUDs. The agency said it would continue to rely on post market requirements including Good Manufacturing Practice (GMP), medical device reporting, registration with the FDA, and labelling requirements. The FDA also stated it would continue to inspect reprocessing facilities with follow up regulatory action being taken as appropriate. Submission of data on adverse outcomes was encouraged along with the evaluation of the effects of cleaning on device performance and material composition.

A 1998 survey of OR managers indicated that over a four year period the reuse of SUDs had almost doubled. Approximately 60% of the managers surveyed reported the reuse of selected SUDs, and 40% reported the reuse of items opened and not used.

The increase in reuse of SUDs raised questions about infection control, patient safety, informed consent, and the need for equitable regulation of the both the OEMs and the reprocessors. These events prompted the FDA to investigate reuse and issue guidance for all entities that were involved in reuse of SUDs, including hospitals and 3rd party reprocessors. The FDA conducted outreach to the various stakeholders from May 1999, resulting in the issue of draft guidance documents in August 2000: "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals". In the final guidance document, the FDA made clear its policy on the issue of the reuse of medical devices labelled for single-use with the primary goal of protecting the health of the public by ensuring that the practice of reprocessing and reusing SUDs was safe and effective, based on sound scientific evidence and held to the same standard as that of the manufacturing. In the meantime, the House of Representatives (Congress) Committee for Commerce Sub-committee for Oversight and Investigations called for a report, which was delivered by FDA Director Feigal days later.

Subsequent documents were published by the FDA in 2003 and 2005 to provide guidance for the industry and FDA staff to supplement and clarify related guidance and regulations. The FDA guidance sought to equitably apply existing regulations to original equipment manufacturers (OEMs), 3rd parties and hospitals to minimise risks associated with reprocessed SUDs. In terms of these, all entities that reprocess SUDs are required to obtain clearance or approval from FDA (e.g. registration requirements and, for each device, submission of an application for either a 510(k) clearance or PMA [premarket approval]).

In October 2002, the FDA's Medical Device User Fee and Modernization Act (MDUFMA) was signed into law. It imposed a number of additional requirements to further regulate the reuse of SUDs:

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• Additional supporting documentation for certain devices that were currently being marketed and had already received 510(k) clearance; and
• Submission of additional validation data with certain new 510(k) submissions.

The additional validation data includes cleaning and sterilization data and functional performance data demonstrating that each SUD will remain substantially equivalent to its predicate (i.e., original) device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

Additional regulations were imposed by the MDUFMA, which amended certain sections as of August 2006; for all reprocessed SUDs, the reprocessor must be identified through a mark on the device or attachment (e.g. detachable label). MDUFSA also required FDA to modify the mandatory and voluntary MedWatch forms to include boxes indicating whether a device was a reprocessed "single-use" device and the name of the reprocessor. In terms of MDUFMA and MDUFSA, the device reprocessed is to the same standard as the original (validated) and is subject to the same price structure. A further statement was issued by FDA Director Shultz before the Committee on Government Reform in September 2006.

The decision to reprocess SUDS is made by each healthcare facility hospital. A multi-departmental reprocessing team ought to be established to gather relevant information and investigate the feasibility of reuse of SUDs. Membership of this committee may include staff from materials management, risk management, infection control, clinical/patient care, safety, administration, legal, and public relations.

The selection of a third party reprocessor is dependent upon certain key issues. They include:
• Safety – All reprocessors are required to be compliant with all FDA requirements as outlined in their August 2000 guidance document, including the Quality System Requirements (QSR). FDA inspection reports may also be reviewed.
• Selection – the broader the range of devices and the method of reprocessing utilised for the devices will yield the greatest savings.
• Support – The method for collecting devices at the hospital should be flexible, efficient and user-friendly.
Other considerations include: type and frequency of on-site support, reporting capabilities (e.g. types of quality reports, certificate of liability insurance, and device tracking capability).

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The US Government Accounting Office (GAO) issued a report to Congress in June 2008 which noted that the FDA had analysed its data on reported adverse events related to reprocessed SUDs and concluded that there were no patterns pointing to these devices posing risks greater than those consistent with the historical record for the predicate devices. After reviewing FDA's processes for monitoring and investigating its adverse event data, the GAO found no reason to question the FDA's analysis. The GAO further noted that the single-use label does not mean a device cannot be reused, simply that the manufacturer has chosen not to conduct the studies (or take steps) necessary to prove that the device is reusable.

Europe

In the Eurozone, there are parallels with the American situation, as there are throughout the world. The principle difference being that the EU government does not have powers to enforce legislation, regulations and policies over all the member states to the degree that the Federal government has in the USA.

As in the USA, pressure to curtail costs that were rapidly escalating with the introduction of evermore sophisticated technology, weighed heavily on healthcare providers. Many institutions and organisations took to reprocessing selected SUDs. As in the USA, this reprocessing was unregulated, poorly policed and a source of concern for the safety of patients by the authorities. Differences of opinion and protracted bureaucratic processes led to the matter progressing to a point where reprocessing was widespread and problematic.

One by one, the more pragmatic members adopted a stance of investigating the practice and apprising themselves of the facts, then deciding whether to approve the practice or not. Germany, Austria, Netherlands, Belgium, Sweden and Denmark decided to approve it. Eventually, sufficient support gathered from interested members for the matter to be put to the EU parliament by the commission on the basis of section 12 of MDD 93/42/EEC. This led to the delegation of an investigation of the practice to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Medical Device Experts Group (MDEG), among others. A formal report was issued by the Commission in 2010.

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The EC report of 2010 noted several concerns but stated the matter required more investigation. It should be noted that the EC report focused only on hospital reprocessing of SUDs and did not consider regulated, third-party reprocessing during its investigation. Subsequently, the matter progressed to the point of the MDEG recommending revision of MDD 93/42/EEC to accommodate reprocessing of SUDs in February 2012. This resulted in a proposal by the EC for a revision of MDD 93/42/EEC phrased to allow reprocessing of SUDs without prejudicing any member's discretion not to do so. Several members, including UK, France and Spain prohibit the practice, although none has proven any substantial increase in risk by reprocessing SUDs.

The revision of MDD 93/42/EEC proposed evidences the prevailing opinion, as it was in the USA previously, that any entity that reprocesses any device for resale should be subject to the same controls as the OEM, essentially being classified as a (re)manufacturer. As with the case of the FDA before, even more stringent controls were called for whereby reprocessors should mitigate any possible risks arising from reprocessing as an added step in the "manufacture".

Subsequent European Parliament (EP) proceedings in October 2013 adopted more fundamentalist language, mostly after the intervention of German MEP Roth Behrendt, which was only adopted on the 2nd vote with amendments. In terms of this language, all devices are considered reusable unless specifically added to a specially created register of single use devices, which would require acceptance by the EC, through the Medical Device Coordination Group (MDCG), of valid scientific or practical reasons to be so registered. Single use devices would be strictly just that, with reuse prohibited.

The implications are massive, since this throws the current classification system into complete disarray. In terms of existing legislation, OEMs must take extra measures to assure reusable devices are safe and suitable for reuse, from which they are exempt should they choose to declare the devices single use. This does not mean all the current SUDs are indeed not reusable, or that they are all not possible to reuse; current accepted wisdom holds that some devices are indeed not suitable for reuse and these were recognised in earlier considerations, including those by the FDA. It is very likely these devices would feature on the special single use register, it remains to be seen which others are accepted on said register.

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More recently, we have learned on good authority that the current European Parliament language has been challenged and there is a good possibility that language previously suggested by the MDEG, and accepted by the Commission, will be incorporated; this would be more closely aligned with current US legislation. It is also likely that, should the current language remain largely unaltered, a reasonable transitional period will be implemented during which current classification of SUDs will hold. It is thought that the European Council will finalise its legislation regarding reprocessing (as part of the larger recast of the medical device directive) by the end of 2015 or early in 2016.

South Africa

In SA, compliance with the MDD 93/42/EEC and the CE mark are prerequisite requirements only for licensing or the import of any medical device listed in the Hazardous Substances Schedule under Act 15 of 1973 (as amended) under Groups III or IV. In some cases, usually with radiological equipment, FDA clearance is also required. Two regulations should be read in conjunction with Act 15 of 1973, viz. R 690 of 1989 detailing regulations relating to group III items and R 1302 of 1991 providing a generic listing of items. In respect of the amendments to MDD 93/42/EEC at least, the revised criteria put forward by the EP for declaring a device single use will effectively open the way to reprocess those SUDs that would in any case have been eligible for reprocessing in terms of previous amendments proposed by the Commission.

Other legislation pertaining to medical devices in SA is the Medicines and Related Substances Control Act 101 of 1965 (as amended), the most recent amendment to which, Act 72 of 2008, gave the most specific definition of medical devices to date and made provision for the establishment of a new authority, South African Health Products Regulatory Authority (SAHPRA) to oversee and regulate both medicines and devices for the first time; however, this Act was not implemented due to legal technicalities and will be revised when implemented by the Medicines and Related Substances Amendment Bill (Bill 6) issued in February 2014. Currently, there is also a draft of Medical Devices Regulations gazetted on 22nd April 2014 which was open to public comment for 90 days.

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Although a single use device is defined in the ***draft*** regulations[1], it is phrased in terms of "intended not to be reprocessed"; it is not defined in terms of broad identifying characteristics or delimitations, design parameters, material characteristics, usage or purpose factors, handling, processing or disposal techniques or methods, manufacturing techniques or methods, accreditation, certification or licensing criteria, absolute prohibition of reprocessing per se or any other legal considerations. A device may be declared by the OEM to be a SUD in South Africa to protect local commercial interests when in Europe the device has not been accepted on the register of SUDs or the device is declared, certificated as or licensed as reusable in any other country in the world.

The ***reprocessing*** of SUDs or prohibition thereof is currently still neither specifically described, nor prohibited, nor contra-indicated, nor legislated nor regulated per se. Sections exist in the draft that make allowance for "modification"[2] and "refurbishment"[3]. Given the historical predominance of reusable devices and the ***current*** lack of distinction in law between these and SUDs, the decision to reprocess ***currently*** falls to the discretion of the user. The decision to reprocess is also mitigated by the fact that many SUDs were declared such without any change from the previous reusable versions, or were declared SUDs in some countries but not in others, or were admittedly declared such for commercial reasons or simply to avoid liability and/or costs (see FDA and GAO resources); ultimately, ***the decision to declare a device a SUD currently rests with the manufacturer and is not mandated***.

1 Draft Medical Devices Regulations – "single use device" means medical device or IVD that is intended to be used on an individual user during a single procedure and then disposed of and which is not intended to be reprocessed and used again;
2 "modification" in terms of a medical device or IVD means any significant change in the medical device or IVD or any change in the purpose thereof where significant change may include the manufacturing process, facility or equipment, the quality control measures used to control the quality and sterility of the medical device or IVD or of the materials used in manufacture, the design of the medical device or IVD, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories and the intended use of the medical device or IVD including any new or extended use, any addition or deletion of a contra-indication of the medical device or IVD and any change to the period used to establish its expiry date;
3 "refurbished medical device" means a medical device the whole or any part of which has been substantially rebuilt, re-equipped or restored, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the original owner of the device, and without prejudice to the generality of the foregoing, a refurbishment of a medical device may involve any or all of the following actions, including, but not limited to, repair, rework, update of software/hardware and replacement of worn parts with parts approved for use by the original manufacturer, performed in a manner consistent with product specifications and service procedures defined by the original manufacturer for that type of equipment without significantly changing the finished equipment's performance, safety specifications and/or intended use as defined in its original registration;

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Recently, the Department of Health (DoH) requested the SABS to establish a sub-committee under Technical Committee TC1039 to draft a code of practice for reprocessing SUDs: ARP 033:20XX. Enquiries to DoH facilitated by the IDC also established that the DoH considers such reprocessing to be permissible and that they consider the third party reprocessor to be a manufacturer[4] for purposes of regulation.

MediQ SA's Viewpoint

- The ***benefits accorded*** by ***SUDs should not be compromised***, these include:
  - A device with ***out-the-box conformity to standards harmonised in MDD/93/42/EEC or 21CFR 801 - 821***.
  - A device ***validated in terms of all the SHERQ systems*** and procedures ensconced ***in*** the ***MDD/93/42/EEC and CE mark or 21CFR 801 - 821***.
  - The ***high standard*** attained by the device should be ***consistent*** and ***independent of*** the ***conditions*** or circumstances prevailing ***at*** the ***place and time*** where it is ***used***.
  - The expectation that the device will ***perform as new***, faultlessly, ***every time***.
  - A device ***out-the-box*** that is substantially ***the same as any other*** random ***example*** of that device out-the-box, ***within*** the ***fine tolerances*** of modern industrial technology.
  - A device with the ***requisite*** type or form of ***packaging and labelling*** and supplied ***with the*** manufacturer's ***instructions for use*** readily at hand out-the-box.
    - A device being ***used according to manufacturer's instructions and/or labelling without*** risk of ***ambiguity*** of interpretation.

- In order ***to achieve the above***, we concur with the stipulations enforced by the FDA and those recommended by the Medical Devices Expert Group (MDEG) to the EC in 2012, i.e. that ***the SUD be rendered to substantially the same state as the original device in every respect***, ***including*** the ***validation of function*** and ***form,*** material and structural ***patency*** as well as ***sterility***, with ***new packaging*** of a similar type or form to the original, ***new labelling*** and ***new instructions*** for use/handling.

4 Draft Medical Device Regulations – "manufacturer" means – (b) any other person who assembles, packages, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device or IVD with a view to their being placed on the market under the natural or legal person's own name, apart from a person who assembles or adapts medical devices or IVDs already on the market to their intended purpose for patients;

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- We believe the ***methods used to render the SUD substantially the same as the predicate device*** should logically follow ***the same approved and validated*** methods ***by which the predicate device was rendered fit*** for use; this includes having ***all*** the ***relevant systems and procedures***, as well as ***technology and equipment***, in place ***with accreditation*** and ***validation***, substantially similar to that used by the OEM to mitigate risk and provide compelling medico-legal defence as well as to address emotive or moral arguments.
    - For more insight into reprocessing methodology and technology, please refer to the following websites:
        - http://sustainability.stryker.com/sustainability-tv and
        - http://youtu.be/nKiUuTNu7WY.
    - Further information is available on the FDA website:
        - http://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofsingle-usedevices/default.htm .
        - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070642.pdf .

Tracking, Tracing and UDI

We plan to make use of cutting-edge technology to track and trace our products through every phase of their reprocessing and use, whereafter they will join the medical waste stream in the normal manner. Since we are to assume the responsibilities of the manufacturer for these devices, we will assign to each a unique device identification code (UDI) as prescribed by the Amendment Bill (Bill 6) of 2014 and by means of this, we will monitor when each device was received, to which processes it has been subjected, which validations it has passed, to whom it is supplied and when, as well as how often it has been reprocessed, etc.

NAPPI Coding

Since each remanufactured device will require a UDI and will then be sold at a substantially discounted price in comparison to the original, a new NAPPI code is required by the administrators, Medi Kredit; accordingly we have requested meetings with the various medical insurance scheme administrators to discuss our operations and hear their comments, with a view to reaching an agreement that they would be willing to reimburse such devices; a letter to that effect is required to initiate coding under the NAPPI system. To date, three of the largest four scheme administrators, accounting for 57% and 88% of current market volume respectively, have agreed in principle to reimburse SUDs reprocessed in the manner we describe.

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Product Prospectus

For your convenience, we have attached a list of devices commonly reprocessed in the USA (Appendix A). Since the user health establishment is required to establish a committee on reprocessing in terms of current best practice as well as the SABS draft code of practice, and since they too are the providers of relevant used stock, we have taken the route of approaching each group or institution to ascertain and discuss their relevant device usages, preferences and requirements, so that we can agree in each case on a list of devices of which they will avail themselves; such a list may include all or only some of the devices on the attached list as well as some other devices not currently on said list.

Standards

Our facility, equipment and operations will apply and comply with the attached list of standards and normative references (Appendix B) as and where applicable. Although Good Manufacturing Practices (GMP) are not currently described for medical devices in SA, MediQ will adapt those set out in European Commission Directive 2003/94/EC until such time as the relevant GMP is amended or a new version is issued in SA.

MediQ will acquire certification under the following standards:

- ISO 9001:2008 Quality management systems
- EN ISO 13485:2012/ AC:2012 Medical devices - Quality management systems
- ISO 14644:1999 Cleanrooms and associated controlled environments
- ISO 14698:2003 Cleanrooms and associated controlled environments -- Biocontamination control
- ISO 14971: 2007 Medical devices -- Application of risk management to medical devices

We look forward to your response and welcome any further queries.

Yours sincerely,

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Appendix A

LIST OF COMMONLY REPROCESSED DEVICES

Device Classification	**Device Types**
Cardiovascular	Blood Pressure Cuffs/Tourniquet Cuffs Cardiac Stabilization and Positioning Devices Diagnostic Electrophysiology (EP) catheters – Steerable and Fixed Curve Electrophysiology Cables Femoral Compression Devices (Femstops) Pulse Oximeter Sensors Sequential Compression Devices (SCD/DVT Sleeves) Ultrasonic Electrophysiology Catheters
Arthroscopic/Orthopaedic	Arthroscopic Burrs, Bits and Blades External Fixation Components including Carbon Fibre Rods, Clamps and Bolts
General Surgery	Balloon Inflation Devices Infusion Pressure Bags Phacoemulsification Tips Reamers

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	Scissor Tips Soft Tissue Ablators Suture Passers
Gastroenterology	Biopsy Forceps – cold
Laparoscopic Surgery	Endoscopic Trocars and Components Harmonic Scalpels Laparoscopic Instruments including Babcocks, Dissectors, Graspers and Scissors/Shears – Hot
Opened-But-Unused and Expired Devices	Company specific limitations

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Appendix B

LIST OF STANDARDS AND NORMATIVE REFERENCES

EN 556-1:2001/ AC:2006 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
EN 556-2:2003 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 2: Requirements for aseptically processed medical devices
EN 1618:1997 Catheters other than intravascular catheters - Test methods for common properties
ISO 9000:2005 Quality management systems -- Fundamentals and vocabulary
ISO 9001:2008 Quality management systems -- Requirements
ISO 10993-1:2009/ AC:2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
ISO 10993-9:2009 Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-13:2010 Biological evaluation of medical devices -- Part 13: Identification and quantification of degradation products from polymeric medical devices
ISO 10993-14:2001 Biological evaluation of medical devices -- Part 14: Identification and quantification of degradation products from ceramics
ISO 10993-15:2000 Biological evaluation of medical devices -- Part 15: Identification and quantification of degradation products from metals and alloys
ISO 10993-16:2010 Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and leachables
ISO 10993-17:2000 Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2005 Biological evaluation of medical devices -- Part 18: Chemical characterization of materials
ISO 10993-19:2006 Biological evaluation of medical devices -- Part 19: Physico-chemical, morphological and topographical characterization of materials
ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11138-1:2006 Sterilization of health care products -- Biological indicators -- Part 1: General requirements

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ISO 11138-2:2006 Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
ISO 11138-3:2006 Sterilization of health care products -- Biological indicators -- Part 3: Biological indicators for moist heat sterilization processes
ISO 11139:2006 Sterilization of health care products – Vocabulary
ISO 11140-1:2005 Sterilization of health care products -- Chemical indicators -- Part 1: General requirements
ISO 11140-3:2007 Sterilization of health care products -- Chemical indicators -- Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
ISO 11140-4:2007 Sterilization of health care products -- Chemical indicators -- Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration
ISO 11140-5:2007 Sterilization of health care products -- Chemical indicators -- Part 5: Class 2 indicators for Bowie and Dick-type air removal tests
ISO 11607-1: Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2006/ AC:2009 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 13408-1:2008 Aseptic processing of health care products -- Part 1: General requirements
ISO 13408-2:2003 Aseptic processing of health care products -- Part 2: Filtration
ISO 13408-6:2005 Aseptic processing of health care products -- Part 6: Isolator systems
ISO 13408-7:2012 Aseptic processing of health care products -- Part 7: Alternative processes for medical devices and combination products
EN ISO 13485:2012/ AC:2012 Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14161:2009 Sterilization of health care products -- Biological indicators -- Guidance for the selection, use and interpretation of results
ISO 14644-1:1999 Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness
ISO 14644-2:2000 Cleanrooms and associated controlled environments -- Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 14644-3:2005 Cleanrooms and associated controlled environments -- Part 3: Test methods

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ISO 14644-4:2001 Cleanrooms and associated controlled environments -- Part 4: Design, construction and start-up
ISO 14644-5:2004 Cleanrooms and associated controlled environments -- Part 5: Operations
ISO 14644-7:2004 Cleanrooms and associated controlled environments -- Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
ISO 14644-8:2013 Cleanrooms and associated controlled environments -- Part 8: Classification of air cleanliness by chemical concentration (ACC)
ISO 14644-9:2012 Cleanrooms and associated controlled environments -- Part 9: Classification of surface cleanliness by particle concentration
ISO 14644-10:2013 Cleanrooms and associated controlled environments -- Part 10: Classification of surface cleanliness by chemical concentration
ISO 14698-1:2003 Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
ISO 14698-2:2003 Cleanrooms and associated controlled environments -- Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data
EN ISO 14937:2009 Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO 14971: 2007 Medical devices -- Application of risk management to medical devices
ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
ISO 15223-2:2010 Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
ISO 15225:2010 Medical devices -- Quality management -- Medical device nomenclature data structure
ISO 15499:2012 Biological evaluation of medical devices -- Guidance on the conduct of biological evaluation within a risk management process
ISO 15882:2008 Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results
ISO 15883-1:2006 Washer-disinfectors -- Part 1: General requirements, terms and definitions and tests
ISO 15883-2:2006 Washer-disinfectors -- Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
ISO 15883-5:2005 Washer-disinfectors -- Part 5: Test soils and methods for demonstrating cleaning efficacy

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ISO 17665-1:2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 17665-2:2009 Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1
ISO 17665-3:2013 Sterilization of health care products -- Moist heat -- Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization
ISO/TR 18128:2014 Information and documentation -- Risk assessment for records processes and systems
ISO 18472:2006 Sterilization of health care products -- Biological and chemical indicators -- Test equipment
ISO 31000:2009 Risk management -- Principles and guidelines
IEC 31010:2009 Risk management -- Risk assessment techniques
EN 60601-1:2006/ AC:2010 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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