

संदर्भ	दिनांक
एम एच डी 06/ टी - 41,42,50,51, 52,53,54	22 11 2011

तकनीकी समिति: **एम एच डी 06**

पाने वाले का नाम :

- 1 वक्ष एवं हृदय वाहिका शल्यचिकित्सा यंत्र विषय समिति, एमएचडी 06 के सभी सदस्यों को
2. चिकित्सा उपकरण एवं अस्पताल आयोजना विभाग परिषद (एम एच डी सी) के सभी सदस्यों को।
3. रुचि रखने वाले सभी अन्य सदस्यों को।

महोदय (यों),

निम्नलिखित प्रलेख संलग्न हैं-

प्रलेख संख्या - एम एच डी 06 (211)

शीषक - कार्डियोवस्क्युलर आरोपण और कृत्रिम अंग - कार्डिओप्यूलमोनरी बार्डपास एवं एकसट्राकोपोरियल मेम्ब्रेन आक्सीजेनेशन (रू सी एम ओ)

प्रलेख संख्या - एम एच डी 06 (212)

शीषक - कार्डियोवस्क्युलर आरोपण इण्डावास्कूलर युक्तियों भाग-2 वास्कुलर स्पण्ट्स

प्रलेख संख्या - एम एच डी 06 (213)

शीषक - कार्डियोवस्क्युलर आरोपण और कृत्रिम अंगनक्त गैस एक्सचेंजर (आक्सिजनैटर)

प्रलेख संख्या - एम एच डी 06 (214)

शीषक - हृदय वाहिका अन्तरोपण और कृत्रिम अंग - रक्त अपोहक, रक्त निस्स्यंदक एवं रक्त सांद्रक

प्रलेख संख्या - एम एच डी 06 (215)

शीषक - हृदय वाहिका अन्तरोपण और कृत्रिम अंग - रक्त अपोहक, रक्त निस्स्यंदक एवं रक्त सांद्रक के लिए वहि: शारीरिक रक्त चक्र

प्रलेख संख्या - एम एच डी 06 (216)

शीषक - कार्डियोवस्क्युलर आरोपण और कृत्रिम अंग - प्लाज्माफिल्टर्स

प्रलेख संख्या - एम एच डी 06 (217)

शीषक - कार्डियोवस्क्युलर आरोपण और कृत्रिम अंग हार्ड शैल कार्डियोटामी/वेनस रिजवायर प्रणाली (फिल्टर सहित / रहित) और नरम वेनस रिजवायर बैग

कृपया इन मानक मसौदे का अवलोकन करें और अपनी सम्मतियाँ यह बताते हुए भेजें कि अंततः यदि ये मानक राष्ट्रीय मानक के रूप में प्रकाशित हो जायें तो इन पर अमल करने में आपके व्यवसाय अथवा कारोबार में क्या कठिनाइयाँ आ सकती हैं।

सम्मतियाँ यदि कोई हों तो कृपया अगले पृष्ठ पर दिए पत्र में अधोहस्ताक्षरी को उपरिलिखित पते पर भेज दें।

सम्मतियाँ भेजने की अंतिम तिथि : **-24-02-2012**

यदि कोई सम्मति प्राप्त नहीं होती है अथवा सम्मति में केवल भाषा संबंधी त्रुटि हुई तो उपरोक्त प्रलेख को यथावत अंतिम रूप दिया जाएगा । यदि कोई सम्मति तकनीकी प्रकृति की हुई तो विषय समिति के अध्यक्ष के परामर्श से अथवा उनकी इच्छा पर आगे की कार्यवाही के लिए विषय समिति को भेजे जाने के बाद प्रलेख को अंतिम रूप दे दिया जाएगा ।

सधन्यवाद

भवदीय

(राकेश कुमार)

वैज्ञानिक घण्टा एवं प्रमुख (एमएचडी)

सलग्नक : उपरोक्त

**DRAFT IN
WIDE CIRCULATION**

DOCUMENT DESPATCH ADVICE	
Ref	Date
MHD 06 /T- 41,42,50, 51,52,53,54	22-11-2011

TECHNICAL COMMITTEE: MHD 06

ADDRESSED TO:

1. All members of Thoracic and Cardiovascular Surgery Instruments Sectional Committee (MHD 06)
2. All Members of Medical Equipment and Hospital Planning Division Council (MHDC)
3. All others interested

Dear Madam(s)/Sir(s),

Please find enclosed the following documents :

- DOC NO: MHD 06 (211)**
TITLE Draft Indian Standard for Cardiovascular implants and artificial organs—Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)
- DOC NO: MHD 06 (212)**
TITLE Draft Indian Standard for Cardiovascular implants—Endovascular devices-
Part 2: Vascular stents
- DOC NO: MHD 06 (213)**
Draft Indian Standard for Cardiovascular implants and artificial organs—Blood-gas exchangers (oxygenators)
- DOC NO: MHD 06 (214)**
Draft Indian Standard for Cardiovascular implants and extracorporeal systems---
Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators
- DOC NO: MHD 06 (215)**
Draft Indian Standard for Cardiovascular implants and extracorporeal systems---
Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters
- DOC NO: MHD 06 (216)**
Draft Indian Standard for Cardiovascular implants and extracorporeal systems---
Plasmafilters
- DOC NO: MHD 06 (217)**
Draft Indian Standard for Cardiovascular implants and artificial organs ---Hard-shell
cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags

Kindly examine the draft Indian Standard and forward your views stating any difficulties which you are likely to experience in your business or profession, if this is finally adopted as National Standards .

Last date for comments: **24-02-2012**

Comments if any, may please be made in the format enclosed and mailed to the undersigned at the above address. In case no comments are received or comments received are of editorial nature, you will

kindly permit us to presume your approval for the above document as finalized. However, in case of comments of technical in nature are received then it may be finalized either in consultation with the Chairman, Sectional Committee or referred to the Sectional committee for further necessary action if so desired by the Chairman, Sectional Committee.

The documents are also hosted on BIS website www.bis.org.in.

Thanking you,

Yours faithfully,

(Rakesh Kumar)
Scientist'F' & Head (MHD)

Encl: As Above

Note: The technical content of the drafts is not available on website. For details please contact:

Head (MHD)
Bureau of Indian Standards
Manak Bhawan
9 Bahadur Shah Zafar Marg
New Delhi 110002
Email: hmhd@bis.org.in, mhd@bis.org.in

Draft Indian Standard
Cardiovascular implants and artificial organs-Requirements for single-use tubing packs
for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)

ICS NO.11.040.40

Not to be produced without the permission of BIS or used as a Standard	Last Date of Comments:24:02:2012
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Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06

National Forward:
(Formal Clause will be added later)

This Draft Indian Standard which is identical with ISO: 15676:2005 'Cardiovascular implants and artificial organs-Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)' issued by the International Organization for Standardization (ISO) will be adopted by the Bureau of Indian Standards on the recommendation of the Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06 and approval of the Medical Equipment and Hospital Planning Department.

The intent of this draft standard is to ensure that medical grade tubing in single-use tubing packs for the transfer of blood and fluid during the period of cardiopulmonary bypass (CPB) and extracorporeal membrane oxygenation (ECMO) is adequately tested for both safety and function. The user commonly provides the specifications for the tubing pack. Furthermore, the purpose of this International Standard is to ensure that the tubing pack characteristics be appropriately disclosed in the labeling and manufacturing information package. Tubing performance characteristics are specifically addressed within the context of this draft Standard as a component part of a single-use tubing pack.

This draft Standard therefore contains recommended procedures to evaluate such medical grade tubing intended for use during CPB procedures and ECMO. Test procedures to determine the material characteristic, the useful life of the tubing when used in a roller pump, and cleanliness are described. The limits for these characteristics are not specified.

This draft Standard also includes minimum reporting requirements. Ready identification of the performance characteristics should assist the user in the selection of such medical grade tubing for the procedure appropriate to the patient and procedure. This information may be useful in a clinic's quality control process that aims to improve the safety of CPB and ECMP procedures.

Requirements for animals and clinical studies are not included in this draft Standard. Such studies, however, may be part of a manufacturer's system. This draft Standard contains only those requirements that are specific to such medical grade tubing for use during CPB and ECMO.

The text of the ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in the Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the word 'International Standard' appear referring to this standard, they should be read as Indian Standard
- b) Comma (.) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker

Cross References

In this adopted standard, reference appears to certain International Standards for which Indian standard also exist. The corresponding Indian Standard which is to be substituted in their place are listed below along with their degree of equivalence the editions indicated:

International Standards	Corresponding Indian Standard	Degree of Equivalence
ISO 10993-1 Biological evaluation of medical devices- Part 1: Evaluation and testing	IS 12572 : Part 1 : 1994 Biological Evaluation of Medical Devices - Part 1 : Guidance on Selection of Tests	Identical

'The technical committee responsible for the preparation of this standard has reviewed the provision of the following ISO standards and has decided that they are acceptable for use in conjunction with this standard'

ISO 34-1 Rubber vulcanized or thermoplastic – Determination of tear strength – Part 1 General Principles

ISO 527-1 Determination of tensile properties – Part 1: General Principles

ISO 9352, Plastics-Determination of resistance to wear by abrasive wheels

ISO 10993-7 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals

ISO 10993-11 Biological evaluation of medical devices- Part 11 Tests for systemic toxicity

ISO 11134, Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization

ISO 11135, Sterilization of health care products Ethylene oxide –Requirements for development validation and routine control of a sterilization process for medical devices

ISO 11137-1 Sterilization of health care products –Radiation – Part 1: Requirements for development validation and routine control of a sterilization process for medical devices

ISO 11137-2 Sterilization of health care products –Radiation – Part 2: Establishing the sterilization dose Requirements

ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1 Requirements for materials, sterile barrier systems and packaging systems

ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1 Requirements for materials, sterile barrier systems and packaging systems

ISO 11607-2 Packaging for terminally sterilized medical devices – Part 2 Requirements for forming sealing and assembly processes

ISO 14937, Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of sterilization process for medical devices

ASTM D 92-00, Standard test methods for density and specific gravity (relative density) of plastics by displacement

ASTM D1044-99 Standard test method for resistance of transparent plastic to surface abrasion

ASTM D2240-04, Standard test method for rubber property-Durometer hardness

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 1960 'Rules for rounding off numerical values (revised). The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft Indian Standard
Cardiovascular Implants- Endovascular devices - Part 2: Vascular stents

ICS NO.11.040.40

Not to be produced without the permission of BIS or used as a Standard	Last Date of Comments:24:02:2012
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Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06

National Forward:
(Formal Clause will be added later)

This Draft Indian Standard (revision of IS 13890) which is identical with ISO: 25539-2: 2008 'Cardiovascular Implants- Endovascular devices - Part 2: Vascular stents' issued by the International Organization for Standardization (ISO) will adopted by the Bureau of Indian Standards on the recommendation of the Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06 and approval of the Medical Equipment and Hospital Planning Department.

This Draft Indian Standard has been prepared in order to provide minimum requirements for endovascular deices and the methods of test that will enable their evaluation.

The text of the ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in the Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the word 'International Standard' appear referring to this standard, they should be read as Indian Standard
- b) Comma (.) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker

Cross References

In this adopted standard, reference appears to certain International Standards for which Indian standard also exist. The corresponding Indian Standard which are to be substituted in their place are listed below along with their degree of equivalence the editions indicated:

International Standards	Corresponding Indian Standard	Degree of Equivalence
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ISO 10993-1:1992 Biological evaluation of medical devices–Part 1: Evaluation and testing	IS 12572 (Part 1): 1994 Biological evaluation of medical devices: Part 1 Guidance on selection of tests (first revision)	Identical
ISO 10993-2:1992 Biological evaluation of medical devices- Part 2: Animal welfare requirements	IS 12572-2:1995 Biological evaluation of medical devices- Part 2 Animal welfare requirements	do

‘The technical committee responsible for the preparation of this standard has reviewed the provision of the following ISO standards and has decided that they are acceptable for use in conjunction with this standard’

ISO 11135-1, Sterilization of health care products Ethylene oxide –Requirements for development validation and routine control of a sterilization process for medical devices

ISO 11137-1 Sterilization of health care products –Radiation – Part 1: Requirements for development validation and routine control of a sterilization process for medical devices

ISO 11607 (both parts), Packaging for terminally sterilized medical devices

ISO 14155 (both parts) Clinical investigation of medical devices for human subjects

ISO 14160, Sterilization of single-use medical devices incorporating materials of animal origin –Valid and routine control of sterilization by liquid chemical sterilants

ISO 14630, Non –active surgical implants – General requirements

ISO 14937, Sterilization of health care products – General requirements for characterization of a sterilization agent and the development, validation and routine control of sterilization process

ISO 14971, Medical devices – Application of risk management to medical devices

ISO 17665-1, Sterilization of health care products – Moist heat-Part 1: Requirements for the development validation and routine control of a sterilization process for medical devices

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 1960 ‘Rules for rounding off numerical values (revised). The number of signified places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft Indian Standard
Cardiovascular implants and artificial organs-Blood-gas exchangers (Oxygenators)

ICS NO.11.040.40

Not to be produced without the permission of BIS or used as a Standard	Last Date of Comments:24:02:2012
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Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06

National Forward:
(Formal Clause will be added later)

This Draft Indian Standard (revision of IS/ISO 7199) which is identical with ISO: 7199:2009 'Cardiovascular implants and artificial organs-Blood-gas exchangers (Oxygenators)' issued by the International Organization for Standardization (ISO) will adopted by the Bureau of Indian Standards on the recommendation of the Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06 and approval of the Medical Equipment and Hospital Planning Department.

This Draft Indian Standard is intended to ensure that devices designed to affect the exchange of gases in support of, or as a substitution for the normal respiratory function of the lungs have been adequately tests for both their safety and function and that extracorporeal device characteristics are appropriately disclosed when labeling the device.

This Draft Indian Standard therefore contains procedures to be used for evaluation of extracorporeal blood gas exchangers (Oxygenators). Type test procedures for determination of the gas transfer, blood cell damage and heat exchanger performance are described, although limits for these characteristics are not specified. Ready identification of the performance characteristics should however, assist the user in the selection of oxygenators that will suit the needs of the patient.

The Draft Indian Standard 1 also includes minimum reporting requirements which will allow the user to compare performance characteristics of oxygenators of different designs in a standard way.

The Draft Indian Standard makes reference to other international Standards in which methods for determination of characteristics common to medical devices can be found.

No provisions have been made for quantification of micro bubble generation of for non-formed element of bovine blood because there currently is no consensus regarding satisfactorily reproducible test methods.

Requirements for animal and clinical studies have not been included in this international Standard. Such studies may be parts of a manufacturer’s quality system.

This Draft Indian Standard contains only those requirements that are specific to oxygenators. Non-specific requirements are covered by references to other International Standards listed in the normative references section. Since non-toxicity is anticipated to be the subject of a future horizontal/level 1 standard this Draft Indian Standard does not cover non-toxicity.

The text of the ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in the Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the word ‘International Standard’ appear referring to this standard, they should be read as Indian Standard
- b) Comma (.) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker

Cross References

In this adopted standard, reference appears to certain International Standards for which Indian standard also exist. The corresponding Indian Standard which are to be substituted in their place are listed below along with their degree of equivalence the editions indicated:

International Standards	Corresponding Indian Standard	Degree of Equivalence
ISO 10993-1:1992 Biological evaluation of medical devices–Part 1: Evaluation and testing	IS 12572 (Part 1): 1994 Biological evaluation of medical devices: Part 1 Guidance on selection of tests (first revision)	Identical

‘The technical committee responsible for the preparation of this standard has reviewed the provision of the following ISO standards and has decided that they are acceptable for use in conjunction with this standard’

ISO10993-7, Biological evaluation of medical devices
Part 7: Ethylene oxide sterilization residuals

ISO10993-11 Biological evaluation of medical devices
Part 11 Tests for systemic toxicity

ISO 11135:1994 Medical devices – Validation and routine control of ethylene oxide sterilization

-ISO 11137-1 Sterilization of health care products –Radiation – Part 1: Requirements for development validation and routine control of a sterilization process for medical devices

ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1 Requirements for materials , sterile barrier systems and packaging systems

ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1 Requirements for materials , sterile barrier systems and packaging systems

ISO 11607-2 Packaging for terminally sterilized medical devices – Part 1 Requirements for materials , sterile barrier systems and packaging systems

ISO 17665-1, Sterilization of health care products – Moist heat-Part 1: Requirements for the development validation and routine control of a sterilization process for medical devices

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 1960 'Rules for rounding off numerical values (revised). The number of signified places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft Indian Standard
Cardiovascular implants and artificial organs – Haemodialysers, haemodiafilters,
haemofilters and haemoconcentrators
ICS NO.11.040.40

Not to be produced without the permission of BIS or used as a Standard	Last Date of Comments:24:02:2012
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Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06

National Forward:
(Formal Clause will be added later)

This Draft Indian Standard (revision of IS/ISO 8637) which is identical with ISO: 8637:2010 'Cardiovascular implants and artificial organs – Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators' issued by the International Organization for Standardization (ISO) will adopted by the Bureau of Indian Standards on the recommendation of the Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06 and approval of the Medical Equipment and Hospital Planning Department.

This Draft Indian Standard is concerned with devices intended for haemodialysis, haemodiafiltration haemofiltration and haemoconcentration in humans. This requirements specified in this Draft Indian Standard will help to ensure safety and satisfactory function.

It was not found practicable to specify materials of construction. This Draft Indian Standard therefore requires only that materials have been tested and that the methods and results and made available upon request. There is no intention to specify, or to set limits on, the performance characteristics of the devices because such restrictions are unnecessary for the qualified user and would limit the alternatives available when choosing a device with the extracorporeal blood circuit specified in IS/ISO8638. The design and dimensions have been selected in order to minimize the risk of leakage of blood and the ingress of air.

This Draft Indian Standard reflects the consensus of physicians manufacturers and other interested parties for devices that are approved for clinical use. Conformance with this International Standard is voluntary and it does not supersede any national regulation.

The text of this ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard.’
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to the following International Standards for which Indian Standard also exists. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with its degree of equivalence for the edition indicated:

<i>International Standards</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 594-2: 1991 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment Part 2: Lock fittings	IS 3234 (Part 2):1995 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment: Part 2 Lock fittings (second revision)	Identical
ISO 10993-1:1992 Biological evaluation of medical devices–Part 1: Evaluation and testing	IS 12572 (Part 1): 1994 Biological evaluation of medical devices: Part 1 Guidance on selection of tests (first revision)	Identical

‘The technical committee responsible for the preparation of this standard has reviewed the provision of the following ISO standards and has decided that they are acceptable for use in conjunction with this standard’

ISO10993-4, Biological evaluation of medical devices Part 7: Selection of tests for interactions with blood

ISO10993-7, Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals

ISO10993-11, Biological evaluation of medical devices Part 11 Tests for systemic toxicity

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 1960 ‘Rules for rounding off numerical values (*revised*). The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft Indian Standard
Cardiovascular implants and extracorporeal systems – Extracorporeal blood circuit for
haemodiafilters, and haemofilters
ICS NO.11.040.40

Not to be produced without the permission of BIS or used as a Standard	Last Date of Comments:24:02:2012
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Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06
National Forward:
(Formal Clause will be added later)

This Draft Indian Standard (revision of IS/ISO 8638) which is identical with ISO: 8638:2010 'Cardiovascular implants and extracorporeal systems – Extracorporeal blood circuit for haemodiafilters, and haemofilters' issued by the International Organization for Standardization (ISO) will adopted by the Bureau of Indian Standards on the recommendation of the Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06 and approval of the Medical Equipment and Hospital Planning Department.

The Draft Indian Standard is concerned with the extracorporeal blood circuit manufactured for single use and intended for use in conjunction with haemodialysers haemodiafilters and haemofilters. The requirements specified in this Draft Indian Standard for the extracorporeal blood circuit will help to ensure safety and satisfactory function.

It was not found practicable to specify materials of construction. This Draft Indian Standard therefore requires only that materials have been tested and that the methods and results and made available upon request.

The dimensions of the connectors intended for connecting the extracorporeal blood circuit to a haemodialyser, haemodiafilter or haemofilter have been specified to ensure compatibility with these devices, as specified in IS/ISO 8637. The design and dimensions have been selected in order to minimize the risk of leakage of blood and ingress of air. Connectors with either fixed or loose locking shells are permitted.

This Draft Indian Standard reflects the consensus of physicians, manufacturers and other interested parties for devices that are approved for cliical use. Conformance with this International Standard is voluntary and it is not intended to supersede any national regulation.

The text of this ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as ' Indian Standard.'
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to the following International Standards for which Indian Standard also exists. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with its degree of equivalence for the edition indicated:

<i>International Standards</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 594-2: 1991 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment Part 2: Lock fittings	IS 3234 (Part 2):1995 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment: Part 2 Lock fittings (second revision)	Identical
ISO 10993-1:1992 Biological evaluation of medical devices–Part 1: Evaluation and testing	IS 12572 (Part 1): 1994 Biological evaluation of medical devices: Part 1 Guidance on selection of tests (first revision)	Identical

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

<i>International Standard</i>	<i>Title</i>
ISO 7864, ISO 10993-4	Sterile hypodermic needles for single use Biological evaluation of medical devices– Part 4: Selection of tests for interactions with blood
ISO 10993-7	Biological evaluation of medical devices–Part 7: Ethylene oxide sterilization residuals
ISO 10993-11	Biological evaluation of medical devices–Part 11: Tests for systemic toxicity

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 1960 'Rules for rounding off numerical

values (*revised*). The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft Indian Standard
Cardiovascular Implants and extracorporeal systems – Plasmafilters

ICS NO.11.040.40

Not to be produced without the permission of BIS or used as a Standard	Last Date of Comments:24:02:2012
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Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06
National Forward:
(Formal Clause will be added later)

This Draft Indian Standard (revision of IS/ISO 13960) which is identical with ISO: 13960:2010 ‘Cardiovascular Implants and extracorporeal systems – Plasmafilters’ issued by the International Organization for Standardization (ISO) will adopted by the Bureau of Indian Standards on the recommendation of the Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06 and approval of the Medical Equipment and Hospital Planning Department.

This Draft Indian Standard contains requirements and acceptance criteria including test methods for safety related parameters for Plasmafilters. Only those requirements that are specific to Plasmafilters have been included. Non specific requirements are covered by references to other Standard listed in Clause 2. This Draft Indian Standard does not cover matters related to toxicity. Such issues are covered in the relevant part of IS 12572.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence the editions indicated:

<i>International Standards</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 594-2: 1991 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment Part 2: Lock fittings	IS 3234 (Part 2):1995 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment: Part 2 Lock fittings (second revision)	Identical
ISO 10993-1:1992 Biological evaluation of medical devices–Part 1: Evaluation and testing	IS 12572 (Part 1): 1994 Biological evaluation of medical devices: Part 1 Guidance on selection of tests (first revision)	do

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

ISO 8637, Cardiovascular implants and artificial organs – Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

ISO10993-4, Biological evaluation of medical devices Part 7: Selection of tests for interactions with blood

ISO10993-7, Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals

ISO10993-11 Biological evaluation of medical devices Part 11 Tests for systemic toxicity

ISO 17665-1, 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 11135-1, Sterilization of health care products Ethylene oxide –Requirements for development validation and routine control of a sterilization process for medical devices

ISO 11137-1 Sterilization of health care products –Radiation – Part 1: Requirements for development validation and routine control of a sterilization process for medical devices

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 1960 'Rules for rounding off numerical values (*revised*). The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft Indian Standard
Cardiovascular implants and artificial organs-Hard-shell cardiotomy/venous reservoir
systems (with/without filter) and soft venous reservoir bags

ICS NO.11.040.40

Not to be produced without the permission of BIS or used as a Standard	Last Date of Comments:24:02:2012
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Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06
National Forward:
(Formal Clause will be added later)

This Draft Indian Standard (revision of IS/ISO 15674) which is identical with ISO: 15674:2009 'Cardiovascular implants and artificial organs-Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags' issued by the International Organization for Standardization (ISO) will adopted by the Bureau of Indian Standards on the recommendation of the Thoracic and Cardiovascular Surgery Instruments Sectional Committee, MHD 06 and approval of the Medical Equipment and Hospital Planning Department.

This standard applies only to the blood reservoir aspect for multifunctional system which may have integral components such as blood-gas exchangers (oxygenators), blood filters, deformers, blood pumps, etc.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in the Indian Standards. Attention is particularly drawn to following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as Indian Standard.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence the editions indicated:

<i>International Standards</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 10993-1:1992 Biological evaluation of medical devices – Part 1: Evaluation and testing	IS 12572-1:1994 Biological evaluation of medical devices: Part 1 Guidance on selection of tests (first revision)	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International standard referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

ISO10993-7, Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals

ISO10993-11, Biological evaluation of medical devices Part 11 Tests for systemic toxicity

ISO 11135:1994 Medical devices – Validation and routine control of ethylene oxide sterilization

ISO 11137-1 Sterilization of health care products –Radiation – Part 1: Requirements for development validation and routine control of a sterilization process for medical devices

ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1 Requirements for materials, sterile barrier systems and packaging systems

ISO 11607-2 Packaging for terminally sterilized medical devices – Part 2 Validation Requirements for forming sealing and assembly processes

ISO 14937, Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of sterilization process

ISO 17665-1, Sterilization of health care products – Moist heat-Part 1: Requirements for the development validation and routine control of a sterilization process for medical devices

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 1960 'Rules for rounding off numerical values (*revised*). The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.