Agfa HealthCare

Essential Principles
(for safety & performance of medical devices)

Orthochromatic Films for Screen Film Radiography

Product information	
GMDN code:	Medical X-Ray Screen Film: 40979 Dental X-Ray Screen Film (extra-oral): 40977
Classification:	Class IIa in accordance to Annex IX Rule 16.of the EU Medical Device Directive.
Intended Use :	An orthochromatic film for Screen/Film Radiography is a non-active device specifically intended for recording of X-Ray diagnostic images.

ROLES AND RESPONSIBILITIES

Owner/Responsible	
QA/RA Representative	Ivan Peeters

Key Author	
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Approval/Accountable	
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To be Informed	
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CONTENT

Revision history

For detailed version history and version numbers, refer to Livelink.

1. Checklist (Annex I)

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
I. GENERAL REQUIREMENTS				
1 The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of the patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include: • reducing as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and • consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	**A**	ISO 13485/ISO 14969 ISO 14971-1 ISO 14155 IEC 62366	**YES**	Agfa's Integrated Management System is compliant with ISO 13485 (cf. IMS-certificates) Agfa's Risk Management procedure is compliant with ISO 14917-1 (18841157). Medical device risk Analysis: (12487992) Usability is addressed in the different verification and validation reports, documented in the project and product workspaces in Livelink.
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: • eliminate or reduce risks as far as possible (inherently safe design and construction), • where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, • inform users of the residual risks due to any shortcomings of the protection measures adopted.	**A**	ISO 13485 ISO 14969 ISO 14971-1 No device specific standards have been identified for this clause	**YES**	Agfa's Integrated Management System is compliant with ISO 13485 (cf. IMS-certificates) Agfa's Risk Management procedure is compliant with ISO 14917-1 (18841157). Medical device risk Analysis: (12487992)

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	**A**	ISO 13485 ISO 14969 ISO 14971-1 ISO 14155	**YES**	Agfa's Integrated Management System is compliant with ISO 13485 (cf. IMS-certificates) Agfa's Risk Management procedure is compliant with ISO 14917-1 (18841157). Medical device risk Analysis: (12487992)
4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	**A**	ISO 13485 ISO 14969 ISO 14971-1 ISO 14155	**YES**	Agfa's Integrated Management System is compliant with ISO 13485 (cf. IMS-certificates) Agfa's Risk Management procedure is compliant with ISO 14917-1 (18841157). Medical device risk Analysis: (12487992)
5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	**A**	ISO 13485 ISO 14969 ISO 14971-1	**YES**	Agfa's Integrated Management System is compliant with ISO 13485 (cf. IMS-certificates) Agfa's Risk Management procedure is compliant with ISO 14917-1 (18841157). Medical device risk Analysis: (12487992) The verification reports contain the simulated check of aging and environmental behaviour The product labels show the storage instructions. PDIP's shows the transport instructions. DHFi Verpakking 28254977

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
6 Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	**A**	ISO 13485 ISO 14969 ISO 14971-1	**YES**	Agfa's Integrated Management System is compliant with ISO 13485 (cf. IMS-certificates) Agfa's Risk Management procedure is compliant with ISO 14917-1 (18841157). Medical device risk Analysis: (12487992)
6.a Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	**A**	ISO 13485 ISO 14969 ISO 14971-1 ISO 14155 No device specific standards have been identified for this clause	**YES**	Agfa's Integrated Management System is compliant with ISO 13485 (cf. IMS-certificates) Agfa's Risk Management procedure is compliant with ISO 14917-1 (18841157). Clinical Data Folder (30269395)
II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION				
7 Chemical, physical and biological properties	**N/A**			Non-active, no-invasive, not intended to come into contact with the patient. There is only limited contact with the hands of the user during handling of the film sheet
7.1 The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to: • the choice of materials used, particularly as regards toxicity and, where appropriate, flammability • the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device, • where appropriate, the results of biophysical or modeling research whose validity has been demonstrated beforehand.				

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
7.2 The devices must be designed, manufactured and packed in such a way as to minimize the risks posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.				
7.3 The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.				
7.4 Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.				

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
Where changes are made to the ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.				
7.5 The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances. If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance to Directive 67/548/EEC, these devices must be labeled on the device itself and/or on the packaging as a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.				

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
7.6 Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.				
8 Infection and microbial contamination	**N/A**			Non-active, no-invasive, not intended to come into contact with the patient. There is only limited contact with the hands of the user during handling of the film sheet. This is not a sterile device
8.1 The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.				
8.2 Tissues of animal origin must originate from animals that have been subject to veterinary controls and surveillance adapted to the intended use of the tissues. Notified Bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regards to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.				
8.3 Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.				
8.4 Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.				
8.5 Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.				

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
8.6 Packaging system for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.				
8.7 The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.				
9 Construction and environmental properties	**A**	ISO 13485 ISO 14969 ISO 14971-1 No device specific standards have been identified for this clause	**YES**	Agfa's Integrated Management System is compliant with ISO 13485 (cf. IMS-certificates) Agfa's Risk Management procedure is compliant with ISO 14917-1 (18841157). Medical X-ray Film needs to be developed to display an anatomic image. Therefore photo-chemicals (developers and fixers) are used in combination with development and eventual handling equipment. Chemistry and Equipment are accessories to the X-ray Film and have no direct impact on the clinical situation of a patient.
9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	**A**	No device specific standards have been identified for this clause	**YES**	See related product brochures. Medical device risk Analysis : (12487992)
9.2 Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: • the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	**A** **A**	ISO 14971-1	**YES** Yes: Medical device risk Analysis : (12485268)	Agfa's Risk Management procedure is compliant with ISO 14917-1 (18841157). Medical device risk Analysis :: (12487992)

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
• risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration; • the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; • risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	**A** **A** **N/A**		Yes: Labeling and AIS contain environmental restrictions for transport and storage Yes: Medical device risk Analysis : (12485268) addresses risks related to unintended exposures	
9.3 Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	**N/A**			
10 Devices with a measuring function	**N/A**			Medical X-ray Film displays an image and has no measuring function. In case where measurements are performed in some clinical practice the practitioners will calibrate the image as the result is dependent on the application and exposure-technique applied.
10.1 Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.				
10.2 The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.				
10.3 The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.				

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
11 Protection against radiation	**A**	ISO 13485 / ISO 14969 ISO 14971-1 No device specific standards have been identified for this clause	**YES**	Medical X-ray Film does not emit X-ray radiation. The sensitivity of the Film influences the dose applied for exposure.
11.1 General **11.1.1** Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	**A**	96/29 EURATOM ISO 9236/1 See Also Clause 11 No device specific standards have been identified for this clause	**YES**	Brochure contains sensitivity class
11.2 Intended radiation **11.2.1** Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	**N/A**			Medical X-Ray film does not emit radiation
11.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	**N/A**			Medical X-Ray film does not emit radiation
11.3 Unintended radiation **11.3.1** Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to emission of unintended, stray or scattered radiation is reduced as far as possible.	**N/A**			Medical X-Ray film does not emit radiation
11.4 Instructions for use **11.4.1** The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risk inherent in installation.	**N/A**			Medical X-Ray film does not emit radiation

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
11.5 Ionizing radiation **11.5.1** Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	**N/A**			Medical X-Ray film does not emit radiation
11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	**N/A**			Medical X-Ray film does not emit radiation
11.5.3 Devices emitting ionizing radiation, intended for therapeutic radiology, shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.	**N/A**			Medical X-Ray film does not emit radiation
12 Requirements for medical devices connected to or equipped with an energy source	**N/A**			Medical X-Ray film is not equipped with or connected to an energy source
12.1 Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.				
12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.				
12.2 Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.				
12.3 Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.				
12.4 Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm system to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.				

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
12.5 Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.				
12.6 Protection against electrical risks				
12.6.1 Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.				
12.7 Protection against mechanical and thermal risks **12.7.1** Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.				
12.7.2 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.				
12.7.3 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.				
12.7.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.				
12.7.5 Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.				
12.8 Protection against the risks posed to the patient by energy supplies or substances.				
12.8.1 Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.				

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
12.8.2 Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.				
12.9 The function of the controls and indicators must be clearly specified on the devices				
12.9.1 Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.				
13 Information supplied by the manufacturer **13.1** Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information compromises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exemption, no such instructions for use are needed for devices in Class 1 or 11a if they can be used safely without any such instructions.	**A**	ISO 13485 ISO 14969 ISO 14971-1 EN 980 ISO 4090 No device specific standards have been identified for this clause	**YES**	Agfa's Integrated Management System is compliant with ISO 13485 (cf. IMS-certificates) Agfa's Risk Management procedure is compliant with ISO 14917-1 (18841157). Medical device risk Analysis : (12487992) Instructions for use are not needed for X-ray Films as it is required to have a dedicated education to perform radiographic investigations. Specifics regarding exposure, combination with screens and developing recommendation are given in the product brochures Codex Film Sizes: 24086141 DHFi Verpakking 28254977

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
13.2 Where appropriate, this information should take the form of symbols. Any symbol or identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colors must be described in the documentation supplied with the device.	**A**	See Also Clause 13.1	**YES**	DHFi Verpakking 28254977
13.3 The label must bear the following particulars:	**A**	See Also Clause 13.1	**YES**	DHFi Verpakking 28254977
(a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative where the manufacturer does not have a registered place of business in the Community;	**A**		**YES**	
(b) the details strictly necessary to identify the device and the contents of packaging especially for the users;	**A**		**YES**	
c) where appropriate, the word 'STERILE';	**N/A**			
d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;	**A**		**YES**	
e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	**A**		**YES**	
f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;	**N/A**		Not marked as single use device, as the use itself prevents re-use.	
g) if the device is custom-made, the words 'custom-made device';	**N/A**			
h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	**N/A**			
i) any special storage and/or handling conditions;	**A**		**YES**	
j) any special operating instructions;	**N/A**			
k) any warnings and/or precautions to take;	**A**		**YES**	
l) year of manufacture for active devices other than those covered by	**N/A**			
(e). This indication may be included in the batch or serial number;	**N/A**			
m) where applicable, method of sterilization.	**N/A**			
n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative	**N/A**			

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	**N/A**			Medical X-Ray films are well known and for lang time established devices.
13.5 Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	**N/A**			Device does not contain components
13.6 Where appropriate, the instructions for use must contain the following particulars:	**A**	See Also Clause 13.1	**YES**	No specific instructions for use are needed. The specific product brochures show all information needed for the user to use it as intended.
a) the details referred to in Section 13.3, with the exception of (d) and (e);	**A**		**YES**	Product specific brochures
b) The performances referred to in Section 3 and any undesirable side-effects;	**A**		**YES**	Product specific brochures
c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;	**A**		**YES**	Product specific brochures
d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration	**N/A**			

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
needed to ensure that the devices operate properly and safely at all times;				
e) where appropriate, information to avoid certain risks in connection with implantation of the device;	N/A			
f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	N/A			
g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilization;	N/A			
h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.	N/A			
Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section 1;				
If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;				
i) details of any further treatment or handling needed before the device can be used (e.g. sterilization, final assembly, etc.);	A		YES	Product specific brochures mention a use of appropriate screens
j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	N/A			
The instructions for use must also include details allowing medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:				
k) precautions to be taken in the event of changes in the performance of the device;	N/A			
l-) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations	A		YES	Labels show environmental storage conditions.

Description	A N/A	Specification/standard Sub clause/reference	Complies YES/NO	Reference Justification and/or comments
in pressure, acceleration, thermal ignition sources, etc.;				
m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;	N/A			
n) precautions to be taken against any special, unusual risks related to the disposal of the device;	N/A			
o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;	N/A			
p) degree of accuracy claimed for devices with a measuring function.	N/A			
q) date of issue or the latest revision of the instructions for use.	N/A			The brochure contains useful information but is not meant as an instruction for use as this part of the education of the user.

2. References – Standards List

ISO 13485: 2003 Quality management standard for medical devices
ISO 14971-1 Medical devices -- Risk management -- Part 1: Application of risk analysis
ISO 14969 Guidance on the application of ISO 13485:2003
IEC 62366 – application of usability engineering to medical devices – v2007 (node ID: 28961709)
ISO 4090:2001 Photography -- Medical radiographic cassettes/screens/films and hard-copy imaging films -- Dimensions and specifications
EN 980 Symbols for use in the labelling of medical devices