付属資料A

<MDD 指令、付属規定I の抜粋>

ANNEX I : ESSENTIAL REQUIREMENTS

絶対的要求

I. GENERAL REQUIREMENTS

全般要求

§ 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 patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their 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.

定められた用法に従い機器が使用されている時、患者、ユーザ、或いは関係する人の安全、健康、臨床条件を危うくするものであってはならない。機器の使用に伴う危険は、患者の利益に見合う妥当なものでなければならず、又、健康及び安全性の十分な保護と両立するものでなければならない。

§ 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.

機器の設計及び組み立ての為に採用される手段は、最新の技術水準を考慮した安全原則に適合したものでなければならない。

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

最適の手段を選ぶに際し、製造者は下記の原則を下記の順序で適用するようにしなければならない。

- eliminate or reduce risks as far as possible (inherently safe design and construction),
  可能な限り危険を排除するか減らすこと(本質的に安全な設計及び組み立てとする事)
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
  排除できない危険に対しては適切な保護手段を講じること。
- inform users of the residual risks due to any shortcomings of the protection measures adopted.
  採用した保護手段の弱点に起因して残る危険に就いてユーザに知らせること。

§ 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.

機器は製造者が意図した性能を達成しなければならない。即ち機器の設計、製造、梱包は、第 1 条 2(a)項に云う一つ又はそれ以上の性能に適するように、又、製造者が指定したように行わねばならない。

§ 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.

機器が通常起こりうるストレスにさらされたとしても、製造者が示す耐用期間内は、上記 1,2 及び 3 項で云う機器の特性や性能は、患者や関係者の安全や臨床条件を危うくするような影響を受けてはならない。

§ 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.
機器の特性、性能が、輸送や保管中に悪影響を受けない様に設計、製造、梱包されなければならない。

§ 6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.
望ましくない副作用は意図した性能・機能に比して受け入れることが出来る範囲のものでなければならない。

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

§ 7. Chemical, physical and biological properties
化学的、物理的、生物学的な特性

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'.
機器は、上記 I の基本要求に云う特性及び性能を保証するように設計製造されなければならない。
Particular attention must be paid to:
特に留意すべきは下記の通り：
- the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,
材料の選定、特に、毒性と可燃性
- the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.
使用材料と、生物組織、細胞及び体液との適合性。機器の目的を考慮すること。

7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk 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.
機器は、汚染物質や残留物が、機器を輸送、保管、使用する人や患者に及ぼす危険を最小限にするように、設計、製造、梱包されなければならない。特に、露出した生物組織、爆露の頻度、機関に、注意を払わなければならない。

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.
機器は、正常使用中或いは通常の処理中に接触する材料、物質、ガスと共に安全に使用できるように設計製造されなければならない。もし医薬品を投与する機器であれば、医薬品に関する規定や制約に基づき医薬品と適合するように、又、意図した性能が維持されるように設計製造されなければならない。

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 65/65/EEC 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, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC.
機器がある物質を構成の一部として内蔵し、その物質が単独で使用されると指令 65/65

第 1 条に定義する医薬品となり、且つ、人体に対する機器の作用を補助する場合、当該物質の安全性、品質、有用性を、指令 75/318 に特定した適切な方法で検証されなければならない。

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.
機器は、機器から漏れ出る物質による危険を最小限にする様に設計製造されなければならない。

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.
機器は、その使用される環境を考慮し、機器の内部に意図せずに入り込んでくる物質に起因する危険を可能な限り減らすように設計製造されなければならない。

§ 8. Infection and microbial contamination
感染及び細菌汚染

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.
機器及び製造工程は、患者、ユーザ、及び第三者に対する感染の危険を可能な限り取り除くか減らすように設計されなければならない。ここで云う設計は、機器の取扱が容易であると共に、患者によって汚染されること、或いは、機器によって患者が汚染されることを最小限にするものでなければならない。

8.2. Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.
動物組織は、意図した用途に適した獣医学的管理及び監視を受けた動物から採取されなければならない。

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 regard to viruses and other transferable 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.
滅菌状態で納入される機器は、再使用できない包装、或いは/及び、販売された際にも滅菌状態に在る様に適切な手順に従って設計製造されなければならない。

8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.
滅菌状態で納入される機器は、適切且つ検証された方法で製造され滅菌されていなければならない。

8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.
滅菌されることを意図した機器は、適切に管理された条件の下で製造されなければならない。

8.6. Packaging systems 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.
非滅菌機器用の包装システムは、規定された清浄レベルを低下させてはならない。使用に先立って滅菌される機器の包装システムは、細菌汚染の危険を最小限にするものでなければならない。

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.
同一或いは類似の機器が、滅菌及び非滅菌の両方の状態で販売される際の機器の包装及び表示はこれらをはっきりと区別できるものでなければならない。

§ 9. Construction and environmental properties

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.
他の機器や装置と組合わせて使用することを意図した機器の場合は、接続システムも含めて全体が安全であって、特定の性能を損なうものであってはならない。

9.2. Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:
機器は、可能な限り下記の危険を除去或いは減らすように設計製造されなければならない：

- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,
機器の体積/圧力比、寸法的、人間工学的特徴も含めた物理的特徴に関係した負傷の危険
- risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,
磁場、外的電気的影響、静電気放電、圧力、温度、気圧変化、加速度といった合理的に予見できる環境条件に関した危険
- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,
研究や治療において通常使用される他の機器との相互干渉による危険
- 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.
保守又は校正が出来ない例えば埋込式機器の場合の様に、使用材料の劣化、測定或いは制御機構の精度の低下に起因する危険

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.
機器は、正常使用及び単一故障状態で、火災或いは爆発の危険を最小限にするように設計製造されなければならない。特に、可燃性物質或いは燃焼を起こす恐れのある物質に露出される機器に注意を払わなければならない。

§ 10. Devices with a measuring function
測定機能を有する機器

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.
測定機能を有する機器は、意図した目的に添った十分な精度と安定性を持つように設計製造されなければならない。精度の限界は製造者が示さなければならない。

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.
測定、監視、表示の目盛りは、人間工学的原則に則して設計されなければならない。
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 (1).
測定機能を有する機器で行った測定は、指令 80/181 の規定に適合した法定単位で表現されなければならない。

§ 11. Protection against radiation
放射線に対する保護
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.
機器は、患者、ユーザ、その他の人の放射線被爆を可能な限り減らすように設計製造されなければならない。但し、治療及び診断目的に適正な放射線レベルを制限するものではない。
11.2. Intended radiation
意図した放射線
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.
特定の医療目的に必要な危険レベルの放射線を放出するように設計された機器で、医療利益が照射による危険よりも大事であると見られる場合は、ユーザにとって放出量を制御できるものでなければならない。そのような機器は、関連の可変パラメータの再現性及び許容度を保証するように設計製造されなければならない。
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.
機器が、潜在的に危険な、可視、不可視の放射線を放出するように設計されている場合、放出に関する視覚表示装置、聴覚警告装置を装備しなければならない。
11.3. Unintended radiation
意図しない放射
11.3.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.
機器は、患者、ユーザ、その他の人が、意図しない放射線や散乱放射に、出来るだけ被爆しない様に設計製造されなければならない。
11.4. Instructions
指示
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 risks inherent in installation.
放射線を放出する機器の取扱説明書には、放射線の性質・特性、患者及びユーザを保護する方法、誤使用防止の方法、据付に固有の危険を除去する方法、に付いての詳細が記述されなければならない。
11.5. Ionizing radiation
電離放射
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.
電離放射線を放出する機器は、放射線の線量、幾何学的分布及び線質が変えられ又制御されるように設計製造されなければならない。

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.
放射線診断を意図した電離放射機器は、患者やユーザの被爆を最小限に押さえながら、医療目的にとって適切な画像や出力品質が得られるように設計製造されなければならない。

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.
放射線治療を意図した電離放射機器は、照射線量、ビームの種類、エネルギー、必要な場合は線質を確実に監視し制御できるように設計製造されなければならない。

§12. Requirements for medical devices connected to or equipped with an energy source
エネルギー源に接続或いは装備した機器に対する要求

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.
電子的にプログラムできるシステムを内蔵する機器は、意図した用途に従って、システムの反復性、信頼性、性能が保証されるように設計製造されなければならない。単一故障が起こったとき、それによって誘発される危険を出来るだけ除去或いは低減する適切な手段が講じられなければならない。

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.
患者の安全性が内部電源に依存する機器は、電源状態を決める手段を装備しなければならない。

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.
患者の安全性が外部電源に依存する機器は、電源故障を知らせる警報システムを装備しなければならない。

12.4. Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.
患者の一つ或いは複数の臨床パラメータを監視する機器は、患者の容体が死亡或いは重症に至るような状態をユーザに警告できる適切な警報システムを装備しなければならない。

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.
機器は、他の機器や装置の動作を損なう電磁場を創り出す危険を最小限に押さえるように設計製造されなければならない。

12.6. Protection against electrical risks
電気的な危険に対する保護
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.

正常使用中や単一故障状態でも、感電の危険が出来るだけ生じない様に、機器は設計製造されなければならない。

12.7. Protection against mechanical and thermal risks
機械的危険、熱的危険に対する保護

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.
患者やユーザを、抵抗力、安定性、可動部分といった機械的な危険から保護するように設計製造されなければならない。

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.
機器が発生する振動から生じる危険を可能な限り低減し、技術進歩にかんがみ発生源で制限するように設計製造しなければならない。但し、振動が特定の性能の為である場合はこの限りに在らず。

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.
機器から発生する騒音から生じる危険を可能な限り低く抑えなければならない。

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.
電気、ガス、水圧、圧縮空気といったエネルギー源への端子や接続器は、起こりうる危険を最小限にするように設計組み立てしなければならない。

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.
機器の可触部及びその周辺部は、危険な温度に達してはならない。

12.8. Protection against the risks posed to the patient by energy supplies or substances
エネルギー供給や物質によって患者に及ぼす危険に対する保護

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.
患者にエネルギーや物質を供給する機器は、フローレイト(流量率)が患者やユーザの安全性を保証するに足る正確さで設定維持できるものでなければならない。

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.
危険を及ぼすフローレイトの不正確さを防止する或いは指示する手段が装備されていなければならない。

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.
エネルギーや物質の供給源から危険なレベルの偶発的な放出が防止される適切な手段が装備されていること。

12.9. The function of the controls and indicators must be clearly specified on the devices.
制御機能及び表示器は機器上に明示されていること。

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.
機器が操作に必要な手順や、操作或いは調整パラメータを視覚的に示している場合、その様な情報はユーザ、場合によっては患者が理解しうるものであること。

§ 13. Information supplied by the manufacturer

製造者が提供すべき情報

13.1. Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users.

安全に使用する為の情報、製造者を識別するための情報が提供されなければならない。

This information comprises 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 exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.

安全取扱説明書は一台一台に同梱しなければならない。

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.

出来れば図記号が望ましい。但し、図記号や識別色は調和規格に適合すること。

13.3. The label must bear the following particulars:

ラベルには下記を表記すること

(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 either the person responsible referred to in Article 14 (2) or of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate;

製造者の名称或いは商標と住所。輸入製品の場合は、第 14 条(2)項の者か、代理人か、又は輸入者の名称及び住所

(b) the details strictly necessary for the user to identify the device and the contents of the packaging;

ユーザが機器及び梱包内容を識別するために必要な情報

(c) where appropriate, the word 'STERILE';

該当する場合、滅菌という語

(d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;

必要な場合、ロット番号或いはシリアル番号

(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;

必要な場合、機器を安全に使用できる期限。年月で表示。

(f) where appropriate, an indication that the device is for single use;

一回限りの使用である旨(使い捨ての意)

(g) if the device is custom-made, the words 'custom-made device';

特注品である場合は、特注機器 'custom-made device'である旨。

(h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';

臨床試験用の場合は、語 'exclusively for clinical investigations

(i) any special storage and/or handling conditions;

特殊な保管や取扱条件

(j) any special operating instructions;

特殊な操作指示

(k) any warnings and/or precautions to take;
必要な警告や注意事項
(l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;
上記(e)以外の能動機器に付いては製造年。
(m) where applicable, method of sterilization.
該当する場合、滅菌の方法。
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.
意図した目的がユーザに明らかでないときは、ラベル上及び取扱説明書中に明確に説明すること
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.
機器及び取り外し可能構成部は、それらによって及ぶ潜在的な危険を検出できるように識別すること。該当する場合は、バッチで識別すること。
13.6. Where appropriate, the instructions for use must contain the following particulars:
取扱説明書には下記を記すこと(該当する場合)
(a) the details referred to in Section 13.3, with the exception of (d) and (e);
13.3 項の詳細。但し、(d)(e)は除く。
(b) the performances referred to in Section 3 and any undesirable side-effects;
3 項で云う性能及び望ましくない副作用。
(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;
意図した目的の為には、他の機器や装置と共に設置したり或いは接続する必要のある機器の場合は、安全な組合わせが行われるように、相手側の機器や装置を正しく識別できる詳細情報
(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 needed to ensure that the devices operate properly and safely at all times;
機器が適切に設置されたかどうか、正しく勝つ安全に動作するかを確認するために必要な情報。加えて、保守及び校正の内容及び頻度に関する情報。
(e) where appropriate, information to avoid certain risks in connection with implantation of the device;
機器の埋め込みに関連して起こりうる危険を回避するための情報
(f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;
特定の調査や治療の間に機器が存在することで及ぼす相互干渉の危険に付いての情報。
(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;
滅菌包装が損傷した場合の必要な指示事項、及び、再滅菌方法の詳細
(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.
再使用が出来る機器の場合、清浄、消毒、包装、再滅菌の為の滅菌方法、再使用回数の制限、と云った再使用をする為に必要な処置に関する情報
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 I;

使用に先立って滅菌を必要とする機器の場合、清浄及び滅菌についての指示情報は、その通りに行われる限り、第 I 節:全般要求への適合が維持されるような内容でなければならない。

(i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);
機器の使用に先立って必要な全ての処理或いは取扱に付いての詳細情報。例えば、滅菌、最終組立等

(j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.
医療目的の為に放射線を放出する機器の場合、放射線の性質、種類(タイプ)、密度/強度、分布の詳細

The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:
更に、取扱説明書には医療スタッフが患者に対して禁忌徴候や事前注意の要点を説明できるように詳細情報を含めること。特に以下の詳細を入れること：

(k) precautions to be taken in the event of changes in the performance of the device;
機器の性能が変わる際の事前注意

(l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;
合理的に予見できる環境条件において、磁場、外部からの電気的影響、静電気放電、圧力或いは圧力変化、加速度、熱的発火源等への曝露に関する事前注意

(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;
医薬品を投与する機器の場合、医薬品及び医薬品選択の制限に関する十分な情報

(n) precautions to be taken against any special, unusual risks related to the disposal of the device;
機器の廃棄の際の特殊かつ異常な危険に付いての事前注意

(o) medicinal substances incorporated into the device as an integral part in accordance with Section 7.4;
本節第 7.4 項に従い、機器の構成の一部として内蔵された医薬物質の詳細

(p) degree of accuracy claimed for devices with a measuring function.
測定機能を備えた機器の場合、精度の階級

§14. Where conformity with the essential requirements must be based on clinical data, as in Section I (6), such data must be established in accordance with Annex X.
絶対的要求適合が臨床試験データによらなければならない場合、その様なデータは付属書Xに従って得られたものでなければならない。