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ANNEX II DIRECTIVE 93 42 EEC WITHOUT SECTION 4 PDF - Search results, B COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices THE COUNCIL OF THE EUROPEAN COMMUNITIES, Having regard to the Treaty establishing the European Economic, Annex II . a) Risk Class I, Note: this is the only classification that qualifies for the self-certification compliance route in the directive. b) Risk Class I plus measuring function c) Risk Class I plus sterilization d) Risk Class IIa e) Risk Class IIb f) Risk Class III . Risk Classifications b) through f) all require assessment and certification by a European Notified Body. Notified Bodies ..., B ANNEX IX CLASSIFICATION CRITERIA I. DEFINITIONS 1. Definitions for the classification rules 1.1. Duration Transient Normally intended for continuous use for less than 60 minutes., SGSGS ;sGscs Ã”iSGsc,s EC Certificate Full Quality Assurance System: GB96/74Å½'Ã‡ Continued SC Sri P3 Medical Limited ,sGsco Directive 93/42/EEC, 6 See point 5.3 of Annex II, point 4 of Annex V and point 4 of Annex VI of Directive 93/42/EEC; point 5 of Annex 2 and point 4 of Annex 5 of Directive 90/385/EEC. In cases of EC type-examination In cases of EC type-examination, 253 ELECTRONIC SIGNATURES DIRECTIVE, DIRECTIVE 1999/93/EC OF 13 DECEMBER 1999 THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, * * * * * Whereas: * * * * (4) Electronic communication and commerce necessitate " electronic signatures" and related services allowing, Slide 1 of 37 Robert Packard, Consultant

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rob@13485cert.com Medical Device Directive (MDD) 93/42/EEC as modified by 2007/47/EC, a survey of the essential modifications Med-Info International expert information for the Medical Device industry It can be concluded that in general there are no dramatic changes but many improvements by better and clearer wording. References are updated and missing definitions are completed. The AIMD remains a separate Directive, but is aligned with the MDD. However, there are remarkable ...,

ATEX Directive 94/9/EC - EUROPEAN DIRECTIVES Removing just one of the 3 elements eliminates the entire risk A C B GENERAL The accidental ignition of an atmosphere containing a large quantity of gas, vapour, mists and/or dust may cause an explosion. Specific measures have been taken on an international level in order to avoid any material damage or the loss of human lives. These measures mainly ..., devices, covered by Directive 93/42/EEC, were regulated in two separate legal instr uments. In the interest of simplification, both directives, which have been amended several times, should be replaced by a single legislative act applicable to all medical devices other than in vitro diagnostic medical devices. (7) The scope of application of this Regulation should be clearly delimited from ..., ICS 23.020.30 Edition February 1998 Pressure Equipment Directive Content Pressure Equipment Directive Annex I Essential safety requirements Annex II Conformity assessment tables, ANNEXES OF THE ASEAN COSMETIC DIRECTIVE Annex II Part 1: List of substances which must not form part of the composition of cosmetic products, (h) Annex II, section 6.2, Annex III, section 7.1, Annex V, section 5.2 and Annex VI, section 5.2 shall be deleted; (i) in Annex XI, section 3 the following sentence shall be inserted after the second sentence:,

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17.11.2009 DIRECTIVES DIRECTIVE 2009/65/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. of 13 July 2009. on the coordination of ..., The Commission shall, no later than five years from the date of implementation of this Directive, submit a report to the Council on the operation of the provisions referred to in Article 10 (1), Article 15 (1), in particular in respect of Class I and Class IIa devices, and on the operation of the provisions referred to in Annex II, Section 4.3 ..., European Medical Device Directive â€“ Essential Requirements Checklist ... Essential Requirements â€“ Annex I, 93/42/EEC as compliance . amended by Directive 2007/47/EC . 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 ..., In the process for the system evaluation acc 93/42/EEC Annex II (without clause 4), Annex V and Annex VI as well as for EC type-examination acc. 93/42/EEC Annex II, clause 4 (Class III devices): This checklist has to be filled out for each device. This document is then part of the documentation which has to be sub-, Such species are listed or may be listed in Annex II and/or Annex IV or V; HABITAT DIRECTIVE . 4 (h) priority species means species referred to in (g) (i) for the conservation of which the Community has particular responsibility in view of the proportion of their natural range which falls within the territory referred to in Article 2; these priority species are indicated by an asterisk (*) in ..., Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma, Council Directive 93/42/EEC on Medical Devices Diagnosis, prevention, monitoring, treatment or alleviation of disease Diagnosis, monitoring, treatment, alleviation of or compensation for injuries or handicaps Investigation, replacement or modification of the anatomy or of a physiological process Conception control. Essential requirements Annex I of the directive requires (examples): that the ..., DIRECTIVES COMMISSION DIRECTIVE (EU) 2016/774 of 18 May 2016 amending Annex II to Directive 2000/53/EC of the European Parliament and of the Council on, 7.7.2018 - eea agreement - annex ii â€“ p. 114 annex ii technical regulations, standards, testing and certification table of contents - part ii, Essential Requirements according to MDD 93/42/EEC; Annex I; Custom-made medical devices . Medentika GmbH manufactures custom-made medical devices pursuant to customer/ordering, Understanding the Machinery Directive (2006/42/EC) Brief History . In 1985, a series of â€˜New Approach Principlesâ€™ were introduced into the European, in Annex II should be coherent, maximise synergies with, ... procedure, according to Council Directive 93/42/EEC of 14 June 1993

concerning medical devices (1) and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (2), which could require the involvement of a notified body designated by competent authorities of Member ..., Annex II Part 1 â€“ List of substances which must not form part of the composition of cosmetic products Version No.: 2018-01 3rd May 2018 ASEAN Cosmetic Documents 1 ANNEXES OF THE ASEAN COSMETIC DIRECTIVE Annex II Part 1: List of substances which must not form part of the composition of cosmetic products, COMMISSION DIRECTIVE 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning, Annex II (EC Declaration of Conformity â€“ full quality assurance system) of Council Directive 93/42/EEC, a.k.a., the Medical Device Directive (MDD) delineates the regulatory requirements necessary for compliance with the Directive employing an acceptable quality assurance system., The Medical Device Directive,published by the European Commission from the European Regulatory Affairs Company, MDSS; a CE Mark Authorized European representative for the Medical Device and In Vitro manufacturing community as per Directive 93/42/EEC - CE Mark, the devices specifically listed in Annex II require a Notified Body, for example PSA is only cancer marker in List B. A Guide to the In Vitro Diagnostic Directive 3, Medical Devices Directive (93/42/EEC) Annex II Full Quality Assurance Annex V Production Quality Assurance ... within which manufacturers may choose either to apply CE Marking under the terms of the Directive or to conform to specific national regulations allowing product to be marketed only where such national regulations are accepted, is given in the Directive. All devices being put on the ..., THE CONSTRUCTION PRODUCTS DIRECTIVE (COUNCIL DIRECTIVE 89/106/EEC) ... ANNEX I: ESSENTIAL REQUIREMENTS ANNEX II: EUROPEAN TECHNICAL APPROVAL ANNEX III: ATTESTATION OF CONFORMITY WITH TECHNICAL SPECIFICATIONS ANNEX IV: APPROVAL

OF TESTING LABORATORIES, INSPECTION BODIES AND CERTIFICATION BODIES Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and ..., DIRECTIVES COMMISSION DIRECTIVE (EU) 2017/2096 of 15 November 2017 amending Annex II to Directive 2000/53/EC of the European Parliament and of the Council on, annexes of the asean cosmetic directive annex ii part 1: list of substances which must not form part of the composition of cosmetic products Understanding The Machinery Directive (2006/42/ec), posing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive., Annex II Part 1 â€“ List of substances which must not form part of the composition of cosmetic products Revision as per August 2015 ASEAN Cosmetic Documents 1 ANNEXES OF THE ASEAN COSMETIC DIRECTIVE Annex II Part 1: List of substances which must not form part of the composition of cosmetic products, stated in the Directive plus Article 5 point 3 (page L174/93) combined with Annex V (page L174/107) where you can find the information and details on how to apply for an, DOWNLOAD ANNEX II DIRECTIVE 93 42 EEC WITHOUT SECTION 4 annex ii directive 93 pdf B COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices THE COUNCIL OF THE, Medical Devices, Annex II excluding (4) No. 5-699-200-1111. This certificate is valid unti I: 2016-11-13 Issued by EMKI as a Notified Body with identification number 1011., The full text of the Directive can be downloaded as a pdf ... The employer shall ensure that the minimum requirements laid down in Annex II are applied to places covered by paragraph 1. 3. Where necessary, places where explosive atmospheres may occur in such quantities as to endanger the health and safety of workers shall be marked with signs at their points of entry in accordance with Annex ..., human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to

be used for a medical purpose., The Manufacturer's Guide to the Revised MDD www.intertek.com 1 Introduction The long-anticipated revisions to the Medical Device Directive (MDD 93/42/EEC) and, Directive 93/42/EEC on medical devices, Annex II (excluding Section 4) For the following products The scope of registration appears on page 2 of this certificate. This certificate is valid from 6 October 2014 until 2 May 2019 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 14 March 2017 Issue 18. Certified since 20 May 1997 Certification is ..., Annex III shall be replaced by the text in Annex I to this Directive; 3. Annex VII appearing in Annex II to this Directive shall be added. Annex VII appearing in Annex II to this Directive shall be added., 93/465/eec: Conformity Assessment Procedures & CE Marking Rules, & Annex (for all products) Guide to Implementation of directives based on new approach & global approach (for all products) 73/23/eec: Directive of Low Voltage Electrical Equipment, ROHS Annex II Dossier for DIBP Proposal for restriction of a substance in electrical and electronic substances under RoHS Final Version Substance Name: Diisobutyl phthalat (DIBP), > DEKRA . Created Date: 8/30/2017 4:40:44 PM, 7.7.2018 - eea agreement - annex ii â€“ p 1 annex ii technical regulations, standards, testing and certification table of contents - part i i motor vehicles, 1 ANNEX DIRECTIVE (EU) 2018/â€¦ OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of amending Directives 2000/53/EC on end-of-life vehicles, 2006/66/EC on batteries and, ANNEX II Directive 93/42/EEC (without section 4) This approval is based on the result of the audit documented in the report dated May 12, 2015 and May 13, 2015. The scope of validity covers the products Hip stem, Hip cup Ballhead CoCr and Ceramic Instruments for hip implants Fixateur Fix-Ex-R The following CE label can be applied to these products mentioned in the Appendix of this certificate ...

langage - Die Apostel Aus St. Jakob - Boy From the Burren - CORAL REEF - Moderna Museet Vargen November 1975 -