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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 10 Novembre 2016  Verslag van de vergadering van 10 November 2016 |

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| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Liste de présence – Aanwezigheidslijst** | | | | | | | **Membres Effectifs**  **Effectieve leden** | P / A = Présent / Aanwezig  E / V = Excusé / Verontschuldigd | **Membres suppléants**  **Plaatsvervangende leden** | | P / A = Présent /  Aanwezig  E / V = Excusé / Verontschuldigd | | | Els Tuyls |  | Marianne Van Malderen | | P / A | | | Awatif Jebari |  | Emmanuelle Gay | | P / A | | | Maries Merken |  | Rita Cornélis | |  | | | Guibert Crèvecoeur |  | Jean-Claude Mignolet | |  | | | Isabelle De Pau ad it. Tom Clarijs | P / A | Annie Vanderlinck | |  | | | Guido Van Nooten | P / A (président) | Yves Taeymans | |  | | | Hein Heidbüchel |  | Rik Willems | |  | | | Kristel De Vogelare |  | Daniel Mojet | | E / V | | | Claude Hanet |  | André Waleff | |  | | | Véronique Kepenne |  | Johan Somville | |  | | | Florence Lefranc |  | Gaetane Stassijns | |  | | | Ludo Willems |  | Dominique Toye | |  | | | Annick Verbiest |  | Philippe Noirhomme | |  | | | Jacques Destiné |  | J-L Vanoverschelde | |  | | | Olivier Debeir |  | Marie-José Tassignon | |  | | | Wim Verlinden |  | Thierry Descamps | |  | | | Dominique Wouters |  | Tinne Leysen | |  | | | Christine Barzin |  | Jan Saevels | |  | | | Anne-Sophie Grell |  | Alex Rijnders | |  | | | Marc Cumps |  | Fien Aerts | |  | | |  |  | Carole Absil | |  | | | Bart Mersseman |  | Marine Debaut | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Damien Lambot | Cedric Vandenbroucke | | Aline Dejehansart | | Julie Roothooft | | Ann Jans |  | |  | |  | |  | | | | | | |  | | | | | | |

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Le président ouvre la réunion à 13h. Le quorum n’est pas atteint.

*De voorzitter opent de vergadering om 13u. Het quorum werd niet bereikt.*

1. **Ordre du jour  / *Dagorde***

Approuvé / goedgekeurd

1. **PV de la réunion précédente / *Verslag van de vorige vergadering***

Eén opmerking van Marianne Van Malderen over het pv van 1 september, in varia op pg 14, 7.1. Dit werd ook reeds opgemerkt tijdens de commissie van oktober. Dit gaat over de aflevering van Abbott Implant. Marianne zal een gecorrigeerde versie doorsturen naar Cédric zodat het aangepast kan worden.

1. **Conflits d’intérêt / *Belangenconflict***

Non / Neen

1. **Suivi des incidents / *Opvolging van de incidenten***

0 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 0dossiers ont été présentés oralement durant cette Commission d’Evaluation

1. **Incidents / Incidenten**

2 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 2 dossiers ont été présentés oralement durant cette Commission d’Evaluation.

51 FSCA sont soumis à la Commission / 51 FSCAs werden voorgelegd aan de Commissie:

* MOSAIQ, IMPAC Medical Systems , Inc. (See FSN 15486)
* Bi-Manual Irrigating / Aspirating Handpieces / Steriseal, ASPEN MEDICAL EUROPE Ltd. (See FSN 17237)
* Catalys Precision Laser System, OPTIMEDICA CORPORATION (See FSN 17781)
* POLYMAILLE EXTRA THIN vascular prosthesis, Perouse Medical (See FSN 17881)
* Cook LapSac Surgical Tissue Pouch, Cook Incorporated (See FSN 17935)
* Socket, hexagonal 0 4.0/11.0 mm, cannulated, for AFN, Synthes GmbH (See FSN 18297)
* Cellistypt, Cellistypt D-K a Cellistypt F, Synthesia, a.s. (See FSN 18901)
* ARCOTANE, Arcadophta (See FSN 19122)
* Puritan Bennett 980 Ventilator, Covidien Healthcare (See FSN 19426)
* Liposuction Cannula, Euromi SA (See FSN 19992)
* Ceka-Preciline, Alphadent NV (See FSN 20065)
* Cortex Screw 4.5mm, self-tapp, L 20mm, Synthes GmbH (See FSN 20107)
* Etermis 2, 3 and 4, Merz Pharmaceuticals GmbH (See FSN 20114)
* HeartWare Ventricular Assist System, HeartWare Inc (See FSN 20199)
* Midas Rex® Sagittal Saws, MEDTRONIC POWERED SURGICAL SOLUTIONS (See FSN 20200)
* Babytherm, Dräger Medical (See FSN 20371)
* M PICC/CVC Securement Device + Tegaderm I.V., 3M Health Care (See FSN 20512)
* APM 440 X, Novacare GmbH (See FSN 20524)
* 2.3MM Tapered Router, Stryker Instruments-Kalamazoo (See FSN 20529)
* neoBLUE LED Phototherapy System, Natus Medical Inc (See FSN 20533)
* Triathlon, HOWMEDICA OSTEONICS Corp. (See FSN 20542)
* Zimmer Air Dermatome II, ZIMMER Orthopaedic Surgical Products (See FSN 20553)
* LAME ONDULEE DE DELBET (Delbet corrugated drain), Laboratoires Peters Surgical (See FSN 20555)
* Adapter for Colibri, for Electric Pen Drive / Adaptor, small, for Colibri II and Small Battery Drive II, Synthes GmbH (See FSN 20559)
* Covidien Valleylab™ Laparoscopic Electrodes, Covidien Healthcare (See FSN 20570)
* Part number 412.812 - Locking Screw Stardrive® Ø 2.4 mm, self-tapping, length 12 mm, Titanium Alloy (TAN) ; Part number 412.812S - Locking Screw Stardrive® Ø 2.4 mm, self-tapping, length 12 mm, Titanium Alloy (TAN) sterile ,Synthes GmbH (See FSN 20580)
* TIGR Matrix Surgical Mesh, Novus Scientific AB (See FSN 20610)
* MultiDiagnost Eleva UroDiagnost, MultiDiagnost Eleva with Flat Detector, Philips Medical Systems Nederland BV (See FSN 20620)
* Passeo-18, Biotronik Ag (See FSN 20623)
* IS4000 EndoWrist? Stapler 45, IS4000 EndoWrist Stapler 30, IS4000 EndoWrist Stapler 30 Curved-Tip, Intuitive Surgical (See FSN 20626)
* Altair, HeliQ, Roomer S, Human Care HC AB (See FSN 20635)
* Laerdal Suction Unit (LSU), Laerdal Medical AS (See FSN 20647)
* PLATINIUM, Sorin Group Italia Srl (See FSN 20658)
* IS4000 EndoWrist Stapler 45, IS4000 EndoWrist Stapler 30, IS4000 EndoWrist? Stapler 30 Curved-Tip, Intuitive Surgical (See FSN 20697)
* LIFEPAK CR® Plus AED and LIFEPAK EXPRESS® AED, Physio-Control (See FSN 20699)
* EnVeo R Delivery Catheter System, Medtronic CoreValve LLC (See FSN 20716)
* Bard® Hydrogel Coated Prostatic Catheter, Bard Medical Division (BMD) (See FSN 20738)
* SMARTABLATE Irrigation Tube Set, Biosense Webster ( A Division of Johnson & Johnson Medical NV ) (See FSN 20762)
* TECNIS Monofocal 1-piece, TECNIS 1-Piece IOL with the TECNIS iTec Preloaded Delivery System, SENSAR Acrylic Monofocal, TECNIS Multifocal 1-piece, TECNIS Symfony Extended Range of Vision Foldable Acrylic 1-Piece, Abbott Medical Optics Inc. (See FSN 20867)
* XPACS Workstation, Xperthis S.A (See FSN 20934)
* TEGO Connector, ICU Medical Inc. (See FSN 20942)
* Ohio Infant Warmer Systems, Datex-Ohmeda Inc (See FSN 20976)
* Proteus 235 and I2C, IBA (Ion Beam Applications) (See FSN 20981)
* Spinocath, B. Braun Melsungen AG (See FSN 20983)
* syngo RT Oncologist, Siemens AG (See FSN 20985)
* Defibrillationselektrode SKINTACT / multifunction defibrillationelectrode, Leonhard lang Medizintechniek GmbH (See FSN 20986)
* various Low Profile products, Biomet 3i (See FSN 20988)
* NON SERILE INTERVERTEBRAL CAGE, Eurospine S.A.R.L. (See FSN 21028)
* REPLAY, ESPRIT, FACIL, KORA, Sorin Group Italia Srl (See FSN 21040)
* OCEANE+ femoral stems, TORNIER SAS (See FSN 21094)
* Pipeline Embolization Device, Alligator Retrieval Device, Marathon Flow Directed Microcatheter, UltraFlow HPC Flow Directed Microcatheter, Xcelerator Hydrophillic Guidewire, Microtherapeutics Inc, ev3 Neurovascular (See FSN 21110)

1. **Etudes cliniques / *Klinische studies***

5 studies werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 5 études ont été présentées oralement durant cette Commission d’Evaluation.

1. **Varia**

Marianne had nog een vraag over Arcotane, gezien de eerdere en gelijkaardige problematiek (visumproblemen) met AlaOcta. Ze vroeg zich af of er een incident met Arcotane heeft plaats gevonden in België. Het is geen incident, maar een FSCA, wat wil zeggen dat het in België enkel ging om een correctieve actie.

**La réunion s’est clôturée à 14h00**

**De vergadering wordt voor gesloten verklaard om 14h00**

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| La prochaine réunion de la Commission d’évaluation des dispositifs médicaux aura lieu le:  *De volgende vergadering van de Evaluatiecommissie voor medische hulpmiddelen gaat door op :*  **01/12/2016 : Salle/Zaal Vivaldi**  à 13h00  *om 13u00* |