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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 03 decembre 2015  Verslag van de vergadering van 03 december 2015 |

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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 | |  | | | Maries Merken |  | Rita Cornélis | |  | | | Guibert Crèvecoeur |  | Jean-Claude Mignolet | |  | | | Maboge Claude ad it. 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 | | P/A | | | 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 | | E/V | | | Anne-Sophie Grell |  | Alex Rijnders | |  | | | Marc Cumps | E/V | Fien Aerts | |  | | |  |  | Carole Absil | | E/V | | | Bart Mersseman |  | Marine Debaut | | P/A | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Driesmans Christophe |  | | Van De Vijver Pieter | |  | | Lambot Damien |  | |  | |  | | Roothooft Julie |  | |  | |  | | Jauniaux Alexandre | | | | | | | Decaluwé Kelly | | | | | | |  | | | | | | |  | | | | | | |

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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***

Approuvé / goedgekeurd

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

Non / Neen

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

0 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / Aucundossier n’a été présenté oralement durant cette Commission d’Evaluation

1. **Incidents / Incidenten**

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

31 FSCA sont soumis à la Commission / 31 FSCAs werden voorgelegd aan de Commissie

* Agility (with Integrity), Elekta Ltd (see fsn 14486)
* Synergy XVI, Elekta Ltd (see fsn 14543)
* Brilliance CT16, Brilliance CT64, Brilliance CT Big Bore Radiology, Brilliance CT Big Bore Oncology, Brilliance iCT, Ingenuity CT, Ingenuity Core, Ingenuity Core128, Ingenuity Flex, Philips Healthcare Ohio (seen fsn 15318)
* Cheek Retractor, f/MatrixMANDIBUL U-shaped, flexi, Synthes GmbH (see fsn 16867)
* Orthopaedic bone screw, non bioabsorbable, sterile, Synthes GmbH (see fsn 17268)
* Gyrus ACMI Diego Elite Tubeset, Gyrus ACMI, inc (see fsn 17738)
* Barco, Barco (see fsn 17858)
* 3M ESPE lava Ultimate, 3M ESPE Dental Products (see fsn 17958)
* Pull Reduction Device fl Percutaneous Drill guide diameter 4.3mm, Synthes GmbH (see fsn 17990)
* Charging Base for surgical Clipper, Medline Industries Inc. (see fsn 18025)
* Medicina Blue Automatic Safety Syringes, Medicina Ltd (see fsn 18050)
* Aequalis IM Nail Targeting Jig, Tornier Inc. (see fsn 18051)
* Evita Infinity V500, Babylog VN500, Evita V300 / Spannungsversorgungseinheit PS500, Drager Medical (see fsn 18110)
* S2000, S3000 with virtual touch IQ option, Siemens Medical Solution (see fsn 18113)
* HeartStart XL+ Defibrillator/Monitor, Philips Medical systems (see fns 18158)
* ACS-NT, Intera 1.5T, Achieva 1.5T, Philips Medical Systems BV (see fsn 18182)
* 882410 GEMINI GXL 16 Slice, 882412 GEMINI LXL, 882470 GEMINI TF 16 Slice, 882471 GEMINI TF 64 Slice, 882473 GEMINI TF Ready, 882473 GEMINI TF Base, 882476 GEMINI TF Big Bore, Philips Healthcare Ohio (see fsn 18198)
* sinus-SuperFlex-635, OptiMed Medizinische Instrumente GmbH (see fsn 18238)
* Pioneer Plus Catheter, Volcano Corporation (see fsn 18275)
* WATCHMAN Left Atrial Appendage (LAA) Closure Device with Delivery System and WATCHMAN Access System, Boston Scientific Corporation (see fsn 18425)
* Contr-Angle CA 1:1 L EVO 15, Bien Air Dental SA (see fsn 18429)
* ON-Q Pump with ONDEMAND Bolus Button, Halyard Health Inc (see fsn 18533)
* CARTOSOUND MODULE, Biosense Webster (see fsn 18561)
* KleenSpec Corded Illumination System, Welch Allyn Inc. (see fsn 18565)
* PenBlade Safety Scalpel, Zien Medical Technologies Inc (see fsn 18607)
* Rpm roll on cuff, Hammarplast Medical AB (see fsn 18689)
* HeartStart MRx Defibrillator/Monitor, Philips Medical systems (see fsn 18736)
* SYDNEY IVF PVP, Willliam A. Cook (see fsn 18740)
* BOLD 2.5mm compression screw, Newdeal SAS (see fsn 18741)
* Amphirion Deep PTA Balloon Dilation Catheter, Invatec (see fsn 18747)
* Luer-Lok syringe, Bulk non-sterile syringe with BD SafetyGlide needle, Oral syringe with BD Eclipse needle, Eccentric Tip syringe, Bulk non sterile Eccentric Tip syringe, Catheter Tip, Bulk non sterile catheter tip, Molnlycke Health Care AB (see fsn 18758)

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

11 études ont été présentées / 11 studies werden gepresenteerd

1. **Varia**
2. Terrafor en Phytosun Dimexanol
3. ALA OCTA

**La réunion s’est clôturée à 13h45**

**De vergadering wordt voor gesloten verklaard om 13h45**

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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 :*  **07/01/2016 : Salle/Zaal Vivaldi**  à 13h00  *om 13u00* |