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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 04 fevrier 2016  Verslag van de vergadering van 04 februari 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 | E / V | Yves Taeymans | |  | | | Hein Heidbüchel |  | Rik Willems | |  | | | Kristel De Vogelare |  | Daniel Mojet | | P / A (Président) | | | 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 | | E / V | | | 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 | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Driesmans Christophe |  | | Van De Vijver Pieter | |  | | Roothooft Julie |  | | Jans Ann | |  | | Vandenbroucke Cédric |  | | Luchian Christina | |  | |  |  | |  | |  | |  | | | | | | |  | | | | | | |

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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 / 0dossiers ont été présentés 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

* Precise Digital Accelerator, Synergy Platform, Synergy, Synergy S, Infinity, Axesse, Elekta Ltd (see fsn 13469)
* Ambient HipVac 50 wand & K-vac wands, ArthroCare Corporation (see fsn 16617)
* RF enabled St. Jude Medical Ellipse, Fortify Assura, Unify Assura, and Quadra Assura Implantable Cardioverter Defibrillators (ICDs) and Assurity and Allure Pacemakers when used with Merlin@home RF Remote Monitoring Transmitter Model EX1150, St Jude Medical (see fsn 16850)
* Cardiosave Hybrid Intra-Aortic Balloon Pump, Datascope Corp. (see fsn 16889)
* Viking 300, Viking M, Viking L, Viking XL, Liko (see fsn 18038)
* Disposable Reflective Marker Sphere (DRMS), Northern Digital Inc. (see fsn 18042)
* GLOBAL 9, Ceramconcept (see fsn 18221)
* Activa PC Neurostimulator, Activa SC Multi-program Neurostimulator, Activa PC+S, Activa RC Multi-Program Rechargable Neurostimulator, Soletra and Kinetra, Medtronic Inc. (see fsn 18226)
* BD Vacutainer Eclipse Signal with Holder, Becton Dickinson (see fsn 18362)
* Lightspeed 16 CT, PET Discovery ST 16, LightSpeed Ultra 16 , PET Discovery LS, and LightSpeed Pro 16, Ge Medical Systems (see fsn 18400)
* Single-Site Maryland Dissector, Single-Site Medium-Large Clip Applier, Single-Site Cadiere Forceps, Single-Site Needle Driver, Single-Site Fundus Grasper, Single-Site Crocodile Grasper, Single-Site Maryland Bipolar Forceps, Single-Site Curved Needle Driver, Single-Site Fenestrated Bipolar Forceps, Intuitive Surgical (see fsn 18510)
* Cardiac Event Recorder, Spacelabs Healthcare Ltd (see fsn 18692)
* CYTO LUER SET, Baxter Healthcare (see fsn 18868)
* Polysafety, Poly Medicure Limited (see fsn 18900)
* Custom Procedure Trays with a Covidien Devon Disposable Light Handle Cover, Medica Europe BV (see fsn 18945)
* VNS Therapy Aspire SR Generator, Cyberonics Inc (see fsn 18960)
* Large Gauge Infiniti Plus Guide (Sold as part of CIVCO brand Needle Guide Starter Kits and Biopsy Starter Kits)

1. Infiniti Plus Needle Guide 12-18 GA

2. Needle Guide Starter Kit

3. Biopsy Starter Kit

4. Sales Demo Kit

Civco Medical Instruments Co (see fsn 18982)

* IntellaTip MiFiTM XP Temperature Ablation Catheter, Boston Scientific Corporation m (see fsn 18987)
* Chariot Guiding Sheath, Boston Scientific (see fsn 19007)
* 8mm endoscope, 0, 8mm endoscope, 30, Intuitive Surgical (see fsn 19015)
* BladderScan BVI 9600 and AortaScan AMI 9700, Verathon Incorporated (see fsn 19016)
* GYNECARE THERMACHOICE III Catheter, Ethicon Women’s Health an Urology, A division Ethicon Inc, A Johnson and Johnson Company (see fsn 19034)
* Endo GIA Ultra Universal Stapler 12mm, Covidien Healthcare (see fsn 19036)
* Forefoot 1.5 set, Newdael SAS (see fsn 19058)
* Kirschner Wire, Synthes GmbH (see fsn 19071)
* Insertion Handle for PFN, Synthes GmbH (see fsn 19073)
* Ambu AuraGain, Ambu (see fsn 19087)
* Concerto & Basic Shower Trolley, ArjoHuntleigh AB (see fsn 19091)
* AspireSR Generator Model 106, Cyberonics Inc (see fsn 19146)
* Philips IntelliVue Information Center iX, Philips Medical systems (see fsn 19160)
* NexGen Precoat/Option Stemmed Tibia, Zimmer Inc (see fsn 19168)

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

9 études ont été présentées / 9 studies warden gepresenteerd

1. **Varia**
2. Aortic Valve Bioprothesis (TAVR & SAVR)

Will be discussed on the following Evaluation commission.

**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 :*  **03/03/2016 : Salle/Zaal Vivaldi**  à 13h00  *om 13u00* |