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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 02 Octobre 2014  Verslag van de vergadering van 02 Oktober 2014 |

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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 | P / A | 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 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 E / V |  | Marine Debaut P / A | |  | | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | | Vanackere Sébastien | Vandenbroucke Cédric | | Van De Vijver Pieter | | |  | | Roothooft Julie | Decaluwé Kelly | | Lambot Damien | |  | | | Dejehansart Aline | Driesmans Christophe | | Eglem Steve | |  | | |  | | | | | | | |  | | | | | | | |  | | | | | | | |  | | | | | | | |

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Le président ouvre la réunion à 13h00. Le quorum n’est pas atteint.

*De voorzitter opent de vergadering om 13u00. 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 mits kleine aanpassing bij varia (Cyberonics)

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

nihil

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

1 dossier werd mondeling gepresenteerd tijdens deze Evaluatiecommissie.

**Dossier 15561:** ThermoCool SmartTouch Uni-Directional Navigation Catheter (Biosense Webster)

1. **Incidents**

Er werden geen nieuwe incidenten besproken.

30 FSCA ont été soumis à la Commission / 30 FSCAs werden voorgelegd aan de Commissie.

* Zimmer Trabecular Metal Reverse Glenosphere Helmet, 36mm / 40mm Instrumentation Used in Shoulder Replacement Surgery (see fsn 13689)
* Getinge 46 series (see fsn 13788)
* Zimmer Trabecular Metal? Reverse Glenosphere Distractor (see fsn 13823)
* Excite F DSC (see fsn 14004)
* EPIQ 7 Ultrasound System (see fsn 14207)
* Manual Orthopaedic Surgical Instruments Instructions of Care, Cleaning, Maintenance and Sterilization (see fsn 14568)
* Infusion sets without needles, transfer sets, extension sets, air inlets, infusion bags (see fsn 14653)
* Zimmer Trabecular Metal Reverse Shoulder System Glenosphere & Base Plate (see fsn 14680)
* Activa PC, Activa PC+S, Activa RC, Activa SC, all Restore devices (including SureScan), PrimeADVANCED, PrimeADVANCED SureScan MRI and Itrel 4 (see fsn 14850)
* Excel 23kHz Disposable Wrench (see fsn 15010)
* Scissors insert "Metzenbaum" (see fsn 15046)
* els flow tip (see fsn 15054)
* ALPHA-PORT / M-CARRIER / M-LIFTING (see fsn 15145)
* Tyvek Self Seal pouches; Tyvek Rolls (see fsn 15186)
* Philips Health Care (see fsn 15222)
* Licox Test Set (see fsn 15355)
* Implant Holder for SynFix-LR (see fsn 15420)
* ArjoHuntleigh Tenor - only versions without scale unit are involved (see fsn 15446)
* Aiming Arm for DFN, combined, for PAD (see fsn 15599)
* CHARLIE GUIDEWIRER HydroFinity (see fsn 15614)
* DIABETES Implantable Insulin Pump MMT-2007D Continuous Tone/Alarm (see fsn 15665)
* Seward Thackray (see fsn 15666)
* Creganna Tactx Medical (see fsn 15709)
* Stentless Biplex Biovalsalva / Thoraflex Hybrid / RVOT Elan / Stented Biplex Biovalsalva (see fsn 15814)
* Celiste PICC-Cel (see fsn 15860)
* Dafilon blue 2/0 (3) 45 cm DSMP 24 (M) (see fsn 15861)
* CloverSnare 4-Loop Vascular Retriever (see fsn 15862)
* Heating unit pad, water, control unit (see fsn 15934)
* Venous Bubble Trap (VBT 160) (see fsn 15975)
* PTFE-Paukenrohrchen / PTFE ventilation tubes (see fsn 15980)
* Perceval Sutureless Heart Valve (see fsn 15982)
* Ellipse VR/DR (see fsn 16056)
* HUDSON RCI SELECT-A-VENT Fixed Diluter Air Entrainment Mask (see fsn 16079)

1. **Etudes cliniques / *Klinische studie***

8 études ont été présentées / 8 studies werden gepresenteerd.

1. **Varia**
2. Datum en uur van de volgende Evaluatiecommissie / Date et heure de la prochaine Commission d’Evaluation

Het FAGG organiseert een FAGG-dag op 06 november in de namiddag. Er werd een nieuwe datum en uur besproken voor de volgende Evaluatiecommissie, die één week later zal doorgaan dan gepland, dus op donderdag 13 november om 13u00.

L’AFMPS organise la journée de l’agence le 6 novembre après-midi, date prévue pour la prochaine Commission d’Evaluation de novembre. Cette dernière est donc reportée au jeudi 13 novembre à 13 heures.

La réunion s’est clôturée à 14h30  
De vergadering wordt voor gesloten verklaard om 14u30.

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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 :*  **13/11/2014 : Salle/Zaal 06D288**  à 13h00  *om 13u00* |