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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 03 Juillet 2014  Verslag van de vergadering van 03 Juli 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 |  | Emmanuelle Gay | |  | | | 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 E / V | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Vanackere Sébastien | Meulders Frédérique | | Dejehansart Aline | |  | | Julie Roothooft | Decalluwé Kelly | |  | |  | | Badisco Liesbeth | Driesmans Christophe | |  | |  | |  | | | | | | |  | | | | | | |  | | | | | | |  | | | | | | |

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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

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

nihil

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

1 dossier a été représenté oralement durant cette Commission d’Evaluation afin de fournir aux membres les éléments qu’ils avaient demandé lors de la commission du 08-05-2014:

dossier 13124: Palacos R+ G 2x40g (Heraeus Medical)

1 dossier werd mondeling toegelicht tijdens deze evaluatiecommissie om de leden de gegevens mee te delen waar ze tijdens de commissie van 08/05/2014 om gevraagd hadden.

Dossier 13124: Palacos R+ G 2x40g (Heraeus Medical)

1. **Incidents**

34 FSCA sont soumis à la Commission / 34 FSCAs werden voorgelegd aan de commissie.

* Schraubadapter (see fsn 11797)
* Precise Treatment Table (no fsn available)
* Integrity (see fsn 13051)
* Ziehm 8000/Vista; Ziehm Compact; Ziehm Vision all, Ziehm Solo (no fsn available)
* OASYS MIDLINE OCCIPUT PLATE (see fsn 13273 & 13274)
* Monaco RTP System (see fsn 13333)
* Sigma Knee System / Sigma tibial inserts compatibility label (see fsn 13652)
* Ceiling Pendant Unit 803x and 603x (see fsn 13829)
* Tec 6 and Tec 6 Plus Vaporizers (see fsn 13876)
* MEDUMAT Transport (see fsn 14081)
* XiO RTP System (see fsn 14537)
* Sola500/700 -display holder arm (see fsn 14687)
* Edi catheter (see fsn 14810)
* Standard Offset Cup Impactor (see fsn 14825)
* Pentaray nav catheter / Pentaray NAv Eco Catheter (see fsn 14862)
* CARESCAPE Monitor B650 and CARESCAPE Monitor B850 (see fsn 14865)
* Evita Infinity V500, Babylog VN500, Evita V300 (see fsn 14924)
* nMARQ Circular and Crescent Irrigated CATHETERS (see fsn 14932)
* Mi1000 PIN Drills (see fsn 15101)
* TRIGEN INTERTAN Nail (see fsn 15226)
* Somatom Emotion 6 / 16 and Somatom Spirit (see fsn 15273)
* Somaton Emotion 2007 (see fsn 15291)
* NavioPFS (see fsn 15294)
* Sola 500/700 (see fsn 15295)
* MobileDiagnost wDR (see fsn 15315)
* Reusable latex breathing bags, test lung (see fsn 15319)
* SERVO-U, SERVO-n (see fsn 15341)
* Codman Programmable Infusion Pump (no fsn available)
* Giraffe Warmer, Panda iRes Warmer, Panda Freestanding Warmer, and Panda Wall Mount Warmer with Nellcor SpO2 (see fsn 15436)
* PATH Thread Cup Adaptor (see fsn 15455)
* Axium Implantable Lead Kit (see fsn 15457)
* Visitec Anterior Chamber Cannula 27G x 7/8 in. (see fsn 15471)
* syngo Imaging (see fsn 15498)
* BONDEK and TEVDEK (see fsn 15535)
* Sarns Malleable Dual-stage Venous Return Cannulae (no fsn available)
* Sarns Disposable Centrifugal Pump (no fsn available)

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

10 études ont été présentées / 10 studies werden gepresenteerd

1. **Varia**

La commission du 7 Août est annulée. De evaluatiecommissie van de 7de augustus is geannuleerd.

La réunion s’est clôturée à 14h00  
De vergadering wordt voor gesloten verklaard om 14u00.

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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 :*  **04/09/2014 : Salle/Zaal 06D288**  à 13h00  *om 13u00* |