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| **Commission d’évaluation des dispositifs médicaux****Evaluatiecommissie voor medische hulpmiddelen**Compte-rendu de la réunion du 03 MARS 2016Verslag van de vergadering van 03 MAART 2016 |

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| **Liste de présence – Aanwezigheidslijst** |
| **Membres Effectifs****Effectieve leden** | P / A = Présent / AanwezigE / V = Excusé / Verontschuldigd | **Membres suppléants****Plaatsvervangende leden** | P / A = Présent / AanwezigE / V = Excusé / Verontschuldigd |
| Els Tuyls  |  | Marianne Van Malderen | P/A |
| Awatif Jebari  | P/A | Emmanuelle Gay  | E/V |
| Maries Merken  |  | Rita Cornélis |  |
| Guibert Crèvecoeur |  | Jean-Claude Mignolet |  |
| Isabelle De Pau ad it. Tom Clarijs  |  | Annie Vanderlinck |  |
| Guido Van Nooten  |  | 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 |  |
| Wim Verlinden |  | Thierry Descamps |  |
| Dominique Wouters |  | Tinne Leysen |  |
| Christine Barzin |  | Jan Saevels  |  |
| Anne-Sophie Grell |  | Alex Rijnders |  |
| Marc Cumps  |  | Fien Aerts |  |
|  |  | Carole Absil  | E/V |
| Bart Mersseman  |  | Marine Debaut  |  |
| **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** |
| Luchian Cristina |  | Van De Vijver Pieter |  |
| Vandenbroucke Cédric |  | Jans Ann |  |
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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 dossier werd mondeling gepresenteerd tijdens deze Evaluatiecommissie / 0dossier ont été présentés oralement durant cette Commission d’Evaluation

1. **Incidents / Incidenten**

1 dossier werd mondeling gepresenteerd tijdens deze Evaluatiecommissie / 1 dossier a été présenté oralement durant cette Commission d’Evaluation

* Dossier 19042: THERMOCOOL SMARTTOUCH Catheter

24 FSCA sont soumis à la Commission / 24 FSCAs werden voorgelegd aan de Commissie

* MHI -TM2000 Linear Accelerator System/ VERO? LlNAC System/ MHI, Mitsubishi Heavy Industries (see fsn 17462)
* Strattice Reconstructive Tissue Matrix, LifeCell Corporation (see fsn 18040)
* FLEXI-SLIP ENDOTRACHEAL TUBE STYLET WITH SOFT DISTAL TIP FLEXISLIP STYLET, STERILE PACK, Teleflex Malaysia Sdn. Bhd Malaysia (see fsn 18409)
* MicroCutter XCHANGE 30 Blue Cartridge, Cardica Inc. (see fsn 18947)
* EchoTip Ultra Endobronchial High Definition Ultra, Cook Ireland (see fsn 19014)
* Bohrlochport, Christophe Miethke GmbH & Co KG (see fsn 19024)
* BD PLASTIK Syringe, BD Oral syringe, ArcRoyal Ltd (see fsn 19045)
* optimys stems lat. TAV 6 & 7 uncem, Mathys AG Bettlach (see fsn 19076)
* Circular Stapler FCSME 32, B.J. ZH.F. Panther Medical Equipment Co, LTD (see fsn 19108)
* VORTEK - Single Loop Ureteral Stent, Coloplast A/S (see fsn 19211)
* BT2000 Manifold Kit, CPT2000 Manifold Kit, Acist Medical Systems, Inc. (see fsn 19212)
* sterile pack. Guide wires, K-Wires , Metaizeau pin, Stryker Trauma GmbH (see fsn 19216)
* Citra-Lock S 4%, Medisp Produtos Hospitalares SA (see fsn 19234)
* Various products, Biomet 3i (see fsn 19243)
* Astral 100 and Astral 150 devices, ResMed Ltd (see fsn 19251)
* Extraction Screw f/PFNA Blade, Synthes GmbH (see fsn 19298)
* TruLight 3000, TruLight 5000, iLED 3, iLED 5, TruV, Trumpf Medizin Systeme GmbH (see fsn 19299)
* Enteral Nutrition ENfit Giving Set, Fresenius Kabi Medical Care AG (see fsn 19312)
* CytoSorb 300mL Device, Cytocell Ltd UK (see fsn 19329)
* HomeChoice Automated PD System and HomeChoice PRO Automated PD System, Baxter Healthcare (see fsn 19331)
* Eclipse Treatment Planning System \_ Eclipse Treatment Planning System, Varian Medical Systems (see fsn 19360)
* Metasul Femoral Head 40 S / -3.5 Taper 12/14, Zimmer GmbH (see fsn 19385)
* Bipolar head Bionit2, Mathys Ltd Bettlach (see fsn 19392)
* Trilogy 100, Trilogy 200, Garbin, Garbin Plus, Trilogy O2, Trilogy 202, Trilogy EC, Philips Respironics (see fsn 19394)
1. **Etudes cliniques / *Klinische studies***

4 études ont été présentées / 4 studies werd gepresenteerd

1. **Varia**
* Silimed

**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 :***14/04/2016 : Salle/Zaal Vivaldi**à 13h00*om 13u00* |