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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 01 Decembre 2016  Verslag van de vergadering van 01 December 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 | P / A | Emmanuelle Gay | |  | | | Maries Merken |  | Rita Cornélis | |  | | | Guibert Crèvecoeur |  | Jean-Claude Mignolet | |  | | | Isabelle De Pau ad it. Tom Clarijs | E / V | 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 | |  | | | Anne-Sophie Grell |  | Alex Rijnders | |  | | | Marc Cumps |  | Fien Aerts | |  | | |  |  | Carole Absil | |  | | | Bart Mersseman |  | Marine Debaut | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Damien Lambot | Cedric Vandenbroucke | | Aline Dejehansart | | Julie Roothooft | | Sibylle Watteeuw  Luchian Cristina | Gregory Duby | | Pieter van de Vijver | | Ann Jans | |  | | | | | | |  | | | | | | |

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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**

4 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 4 dossiers ont été présentés oralement durant cette Commission d’Evaluation

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

* 17400 Stryker Orthopaedics Mahwah, Triathlon Distal Capture Assembly, Stryker Orthopaedics Mahwah (See FSN 17400)
* 18169 Mani Inc MANI Trocar Kit, Mani Inc (See FSN 18169)
* 19238 GE Medical Systems Information Technologies Optima XR220amx, Optima XR200amx, Brivo XR285amx Optima XR220amx, Optima XR200amx, Brivo XR285amx, GE Medical Systems Information Technologies (See FSN 19238)
* 19596 Dexcom Inc. G4 PLATINUM and G5 Mobile receiver, G4 PLATINUM and G5 Mobile receiver, Dexcom Inc. (See FSN 19596)
* 20468 MicroPort Orthopedics Inc. PROFEMUR® Neck PROFEMUR® Neck, MicroPort Orthopedics Inc. (See FSN 20468)
* 20715 Terumo Corporation TOKYO MISAGO® Self-Expanding Stent SystemMISAGO® Self-Expanding Stent System, Terumo Corporation TOKYO (See FSN 20715)
* 20743 Siemens AG syngo RT Therapist, Siemens AG (See FSN 20743)
* 20747 Mölnlycke Health Care AB, ProcedurePak kits and trays containing umbilical clamps ProcedurePak kits and trays containing umbilical clamps, Mölnlycke Health Care AB (See FSN 20747)
* 20755 Philips Medical systems (Andover) IntelliVue Patient Monitor (See FSN 20755)
* 20780 Becton Dickinson and Company BD Vacutainer® Push Button Blood Collection Set (See FSN 20780)
* 20784 IMPAC Medical Systems , Inc. Monaco RTP System Monaco RTP System, IMPAC Medical Systems , Inc. (See FSN 20784)
* 20786 WaisMed Ltd. NIO Intraosseous Device, WaisMed Ltd. (See FSN 20786)
* 20795 LeMaitre Vascular GmbH, Hydro LeMaitre Valvulotome (See FSN 20795)
* 20801 Stryker Orthopaedics Mahwah, Trident Constrained liner Impactor Tips (See FSN 20801)
* 20840 Stryker Orthopaedics Mahwah, Cup Positioner / Impactor Handle Assembly(See FSN 20840)
* 20954 Philips Healthcare Ohio "Brilliance BR64, Ingenuity CT, Ingenuity Core, Ingenuity Core128" (See FSN 20954)
* 21129 MED-EL ELektromedizinische Geräte GmbH, SONNET Rechargeable Battery Pack Cover Micro-Black (See FSN 21129)
* 21167 Telemis Telemis-Medical, Telemis (See FSN 21167)
* 21210 Siemens AG, SOMATOM Definition AS and SOMATOM Definition Flash (See FSN 21210)
* 21214 Philips Medical systems (Andover), MX40 (See FSN 21214)
* 21247 Teleflex medical, Mucosal Atomization Device (MAD) (See FSN 21247)
* 21249 MED-EL ELektromedizinische Geräte GmbH, SONNET Mini Battery Pack Cable (See FSN 21249)
* 21309 Siemens AG, Artis zee systems with SW version VC21C, VD11 (See FSN 21309)
* 21315 Philips Healthcare Ohio "Brilliance iCT SP, Brilliance iCT, Brilliance 64, Brilliance 40, Brilliance16, Brilliance 16P, Brilliance 10, Brilliance 6, Brilliance Big Bore Oncology, Brilliance Big Bore Radiology, Ingenuity Core, Ingenuity Core128, Ingenuity CT" (See FSN 21315)"

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

4 studies werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 4 études ont été présentés oralement durant cette Commission d’Evaluation

1. **Varia**
2. NuSurface

Attendre l’avis des experts pour la génération 2 du dispositif

**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 :*  **12/01/2017 : Salle/Zaal Vivaldi**  à 13h00  *om 13u00* |