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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 06 octobre 2016  Verslag van de vergadering van 06 oktober 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 |  | 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 | |  | | | Bart Mersseman |  | Marine Debaut | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Vandenbroucke Cédric  Duby Grégory  Lambot Damien |  | | Van De Vijver Pieter  Jans Ann  Driesmans Christophe | |  | |  |  | |  | |  | |  | | | | | | |  | | | | | | |

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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***

Remarque de Marianne Van Malderen concernant le point Varia présenté par Thierry Roisin. Il faut faire attention au pharmacien hospitalier qui ne pourront plus prescrire le dispositif aux patient et que la patient soit remboursé.

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 présenté oralement durant cette Commission d’Evaluation

1. **Incidents / Incidenten**

9 dossiers werd mondeling gepresenteerd tijdens deze Evaluatiecommissie / 9dossiers ont été présentés oralement durant cette Commission d’Evaluation

* Dossier 19907 (GDY)
* Dossier 20152 (GDY)
* Dossier 20299 (CCV)
* Dossier 20361 (CCV)
* Dossiers 20394 (CCV)
* Dossier 20469 (CCV)
* Dossier 20648 (DLT)
* Dossier 20670 (DAT)
* Dossier 20760 (CCV)

49 FSCA sont soumis à la Commission d’Evaluation / 49 FSCAs werden voorgelegd aan de Commissie

1. Precise Treatment Table, Elekta Ltd (See FSN 16005)
2. EPIQ 5, Philips Health Care (See FSN 17736)
3. Astral 150, ResMed Ltd (See FSN 17753)
4. Artis zee Floor, Artis zee Biplane, Artis zee MP / AXIOM Artis, Siemens AG (See FSN 17882)
5. Cardiosave Hybrid/Rescue IABP, Maquet Cardiovascular LLC (See FSN 19201)
6. NeoCoil, NeoCoil, LLC (Pewaukee) (See FSN 19501)
7. FRED EASY, Schiller Medical SAS (See FSN 19639)
8. Essure, Bayer Healthcare LLC (See FSN 19669)
9. LightSheer DESIRE, Lumenis Ltd (See FSN 19814)
10. D-Vapor; D-Vapor 3000, Dräger Medical (See FSN 19926)
11. CS ELITE FASTPACK, 225ML, Haemonetics Corp USA (See FSN 19989)
12. Biomet Sports Medicine and Trauma (See FSN 19990)
13. Distal Plug, Biomet France SARL (See FSN 20028)
14. clou diaphysaire EXTREME ; quille longue pour PTG

UNI SCORE® tibial tray for fixed bearing insert – HA coated – cementless

UNI SCORE® tibial tray for mobile bearing insert - HA coated - cementless

UNI SCORE® tibial tray for fixed bearing insert - HA coated - cementless - RM / LL

UNI SCORE® tibial tray for fixed bearing insert - HA coated - cementless - LM/ RL

UNI SCORE® femoral component – HA coated – cementless

EXTREME® diaphyseal nail – HA coated – cementless

INITIALE® modular femoral stem - Cemented

INITIALE® modular dysplastic femoral stem - Cemented

INITIALE® modular revision femoral stem - Cemented

Extension stem for Total Knee Prosthesis - Cemented

Allergy Solution extension stem for Total Knee Prosthesis – Cemented Amplitude (See FSN 20145)

1. Prism0Cal B22, Gambro Dasco Sondalo (See FSN 20300)
2. AUTOPLEX SYSTEM, Stryker Instruments-Kalamazoo (See FSN 20392)
3. Merge PACS, Merge Healthcare (See FSN 20436)
4. Merge PACS, Merge Healthcare (See FSN 20437)
5. ArcRoyal Metalline

BE0120 Thyroid procedure tray, BEA207 Lumbar arthrodesis laminectomy,

BE0290 Breast reduction / abdominoplasty, BE0283 Post merger set, BE0278 Combination set, ArcRoyal Ltd (See FSN 20461)

1. RayStation, RaySearch Laboratories AB (See FSN 20465)
2. PROGRESSA BED SYSTEM, HILL-ROM (See FSN 20467)
3. CONSERVE® Shell

DYNASTY® Metal Liner

PROCOTYL® Metal Liner

LINEAGE® Metal Liner, MicroPort Orthopedics Inc. (See FSN 20470)

1. NIM® Standard Reinforced EMG Endotracheal Tube, NIM Contact® Reinforced EMG Endotracheal Tube, MEDTRONIC XOMED Inc (See FSN 20481)
2. ActiGait(R) Implantable Drop Foot Stimulator, Neurodan (See FSN 20492)
3. Vascu-Guard Peripheral Vascular Patch, Synovis Surgical Innovation (See FSN 20502)
4. STIMPOD NMS410 / NMS450 Neuromuscular Stimulator, Xavant Technology (See FSN 20518)
5. washer/disinfector, Miele Werk Burmoos GmbH (See FSN 20528)
6. AXIOM Artis; Artis zee; Artis Q/Q zen, Siemens AG (See FSN 20576)
7. twinSys double offset adaptor right & left, Mathys Ltd Bettlach (See FSN 20604)
8. WHIPKNOT Soft Tissue Cinch #5 Sutures, Smith & Nephew USA (See FSN 20609)
9. NobPrl CC Guided Surgery Kit, Nobel Biocare AB (See FSN 20625)
10. O-arm® 1000 Surgical Imaging System, O-arm® O2 Surgical Imaging System, Medtronic Navigation Inc. (See FSN 20630)
11. DFM Transcatheter Aortic Valve System, Direct Flow Inc (See FSN 20641)
12. Sterile RENASYS™ Transparent Film, Smith & Nephew (See FSN 20651)
13. Implant rotulien de resurfacage a cimenter diametre 36 mm, Amplitude (See FSN 20698)
14. Lotus Valve System, Boston Scientific Corporation m (See FSN 20719)
15. Standard Offset Cup Impactor, Greatbatch Medical (See FSN 20751)
16. AcrySof® IQ IOL with ULTRASERT™ Delivery System, Alcon Laboratories Inc. (See FSN 20759)
17. T2 Kirschner wire 1p (T2 Kirschner-draad 1x)

MET IM PEN

GAM Kirschner Wire (GAM Kirschner-draad)

G3 K-Wire, UNS-Thread (G3 K-draad, UNS-schroefdraad)

GAM Guide Pin D4xL400 (GAM geleidepen D4xL400)

G3 K-Wire with Washer (G3 K-draad met ring)

T2 K-Wire (T2 K-draad)

K-Wire 3 with Washer (K-draad ?3 met ring)

T2 Guide Wire Ball Tip (T2 voerdraad bol-opzetstuk)

T2 Guide wire (T2 voerdraad)

Guide wire ball tipped (Voerdraad met bol-opzetstuk)

T2 Guide Wire Ball Tip (T2 voerdraad bol-opzetstuk)

T2 Guide wire (T2 voerdraad)

T2 Guide wire (T2 voerdraad)

Guide Wire Ball Tip (Voerdraad bol-opzetstuk)

Fixations K-Draht (K-draad voor fixatie)

T2 K-Wire Recon (T2 K-draad Recon)

T2 K-Wire CoCr Recon (T2 K-draad Recon), STRYKER TRAUMA GmbH (See FSN 20767)

1. Angel Blood Access Kit, Nuo Therapeutics, Inc. (See FSN 20769)
2. Astral 100 and Astral 150 devices., ResMed Ltd (See FSN 20770)
3. Carina350EM

Carina 350EML

Carina 350EE, Handicare AB (See FSN 20777)

1. HeartWare Ventricular Assist System, HeartWare Inc (See FSN 20781)
2. E.CAM and Symbia E family, Siemens Medical Solutions USA, Inc. Molecular Imaging (See FSN 20827)
3. Comfort Shield Barrier Cream Cloths, Sage Products Inc (See FSN 20829)
4. PASCAL Synthesis (532/577) & Twinstar (577/638), Topcon Medical Laser Systems, Inc. (See FSN 20849)
5. Human Care Roomer S and Altair, Human Care HC AB (See FSN 20857)
6. Tandem Bipolar Hip System, Smith & Nephew USA (See FSN 20862)
7. MAGiC application running on some GEHC MR systems, Ge Medical Systems (See FSN 20901)
8. **Etudes cliniques / *Klinische studies***

7 études cliniques ont été présentées / 7 klinische studies warden gepresenteerd

1. **Varia**
   1. Mycobacterium : Explication de la recommandation du CSS à la commission d’évaluation. Bard a également fait une recommandation concernant un de ses dispositif pour ne plus l’utiliser à l’intérieur d’une salle d’opération.

**La réunion s’est clôturée à 14h35**

**De vergadering wordt voor gesloten verklaard om 14h35**

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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 :*  **10/11/2016 : Salle/Zaal Horizon**  à 13h00  *om 13u00* |