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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 12 mei 2016  Verslag van de vergadering van 12 mai 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 | | E/V | | | Maries Merken |  | Rita Cornélis | |  | | | Guibert Crèvecoeur |  | Jean-Claude Mignolet | |  | | | Isabelle De Pau ad it. Tom Clarijs | E/V | Annie Vanderlinck | |  | | | Guido Van Nooten | E/V | 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** | | | | | | | Driesmans Christophe  Decaluwe Kelly |  | | Van De Vijver Pieter  Jans Ann | |  | | Vandenbroucke Cédric  Lambot Damien  Dejehansart Aline  Roothooft Julie  Watteeuw Sibylle |  | | Luchian Cristina | |  | |  | | | | | | |  | | | | | | |

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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**

7 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 7 dossiers ont été présentés oralement durant cette Commission d’Evaluation

* Dossier 19042 (KYD) : ThermoCool SmartTouch
* Dossier 19486 (CCV) : Palacos
* Dossier 18505 (KYD) : HeartWare Ventricular Assist System
* Dossier 19881 (DAT) : HeartWare Ventricular Assist system (HeartWare Inc)
* Dossier 19179 (CDS) : CoreValve
* Dossier 19499 (DLT) : Amplatzer Amulet
* Dossier 19915 (DAT) : Lumax 740 HF-T (Biotronik GmbH & Co)

44 FSCA sont soumis à la Commission / 44 FSCAs werden voorgelegd aan de Commissie

* Monaco, Impact Medical Systems (see fsn 15965)
* Healon EndoCoat Opthalmic Viscosurgical Device, Abbott Medical Optics Inc. (see fsn 16572)
* HeartStart MRx Defibrillator/Monitor, Philips Medical systems (see fsn 16936)
* Philips Expression MRI Patient Monitoring System, Invivo Corporation (see fsn 17871)
* MEDCOMP HEMO-CATH ®LT AND HEMO-CATH ®ST;JET Flow®, Medical Components Inc. (see fsn 18058)
* Sapphire Infusion Pump, Q Core Medical Ltd. (see fsn 18210)
* EASYPUMP II LT 100-50-S, B.Braun Melsungen AG (see fsn 18348)
* Olympus Instrument Channel Adaptor, Olympus Keymed UK (see fsn 18456)
* Sciatic Nerve Retractor, Synthes GmbH (see fsn 18497)
* Gammex PF, Ansell N.P. SDN BHD (see fsn 18554)
* Allura Xper FD, Philips Best (see fsn 18578)
* Brilliance 16-Slice (Air), Brilliance 64 CT, Ingenuity Core, Ingenuity Core128, Brilliance CT Big Bore, Ingenuity Flex (see fsn 18658)
* Gaasdepper, Gaasbollen, Gaaskompres, Jiangsu Province Jianerkang Medical Dressing Co., Ltd (see fsn 18721)
* Gaaskompres 10x10 cm 12L. S10 X-Ray steriel e.o., Jiangsu Province Jianerkang Medical Dressing Co., Ltd (see fsn 18722)
* CREPE BANDAGE, Winner industries Co, Ltd (see fsn 18723)
* KOMPRES GAAS, Winner industries Co, Ltd (see fsn 18724)
* Revolution CT, GE Medical Systems (see fsn 18834)
* SOMATOM DEFINTION AS with Patient Table 1600, Siemens AG (see fsn 18852)
* Völker-Bett 2080, Volker AG (see fsn 18907)
* Extension Device, Orto Maquet (see fsn 19141)
* ala purple, Alamedics GmbH (see fsn 19185)
* Zimmer Periarticular Locking Plate System, Zimmer Inc (see fsn 19186)
* FREKA CONNECT ENLock 5ml, Fresenius Kabi Medical Care AG (see fsn 19213)
* Nutrisafe 2, Laboratoire pharmaceutique Vygon SA (see fsn 19227)
* Dialog+, B.Braun Avitum AG (see fsn 19257)
* HeartWare Ventricular Assist System, HeartWare Inc (see fsn 19267)
* Specify 5-6-5 Surgical Lead and Specify 2x8 Surgical Lead, Medtronic Inc. Minneapolis (see fsn 19284)
* AP Cutting Block Triathlon I AP Cutting Block Scorpio, Spierings Orthopaedics BV (see 19337)
* IntelliVue Patient Monitor, Philips Medical systems (see fsn 19373)
* IntelliVue Patient Monitor, Philips Medical systems (Andover) (See FSN 19373)
* washer/disinfector / Container & Trolleywasher, Miele Werk Bürmoos GmbH (See FSN 19419)
* PVC Trocar Catheter CH 24, REDAX SRL (See FSN 19463)
* Shuttle 2.7; 3.7; 2.7 360; 3.7 360, Trumpf Medizin Systeme GmbH (See FSN 19473)
* DVR ePAK, Biomet Orthopaedics Inc. (See FSN 19506)
* Universal SlingBar, Liko (See FSN 19516)
* Extension Device, Maquet (Rastatt) (See FSN 19539)
* 3M™ Coban™ 2 and 3M™ Coban™ 2 lite, 3M Health Care (See FSN 19570)
* CeraFlex™ Atrial Septal Defect (ASD) Occluder, Lifetech Scientific Ltd (See FSN 19657)
* EVIS EXERA II VIDEODUODENOSCOPE TJF-Q180V, Olympus medical Systems Corporation (See FSN 19789)
* Double joint struts, OR Adapter, OR-Extension, Trumpf Medizin Systeme GmbH (See FSN 19847)
* da Vinci S Surgical System, da Vinci Si Surgical System, da Vinci Xi Surgical System, Intuitive Surgical lnc. (See FSN 19883)
* Biolox Delta Head, 36mm Std Neck, 12/14 Taper, Biomet UK Ltd (See FSN 19896)
* PE ATS BAG LF 6/CS, PE PNEUMONECTOMY LF 6/CS, PE ADULT-PED DRY/ WET LF 6/CS, PE DRY/WET DUAL COLL LF 6/CS, PE INFANT DRY/WET LF 6/CS, PE ADULT-PED WET LF 6/CS, PE ADULT-PED WET LF 6/CS, PE ADULT-PED WET DUAL COLL LF 6/CS, PE MINI SAHARA 6/BX LATEX FREE, PE SAHARA ATS BAG LF 6/CS, PE SAHARA DRY SUCT/DRY SEAL LF 6/CS, PE SAHARA DRY SUCT/DRY SEAL DUAL LF 6, Teleflex medical (See FSN 19905)
* DIRECT DRIVE Clip Applier 3/BX, APPLIED MEDICAL (See FSN 19911)
* M2A 38mm Acetabular System - all cups and heads, Biomet UK Ltd (See FSN 19974)

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

5 études ont été présentées / 5 studies werden gepresenteerd

1. **Varia**

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**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 :*  **02/06/2016 : Salle/Zaal Vivaldi**  à 13h00  *om 13u00* |