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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 14 janvier 2016  Verslag van de vergadering van 14 januari 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 | E / V | 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 | |  | | | 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 |  | Fien Aerts | |  | | |  |  | Carole Absil | | E / V | | | Bart Mersseman | P / A | Marine Debaut | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Driesmans Christophe |  | | Van De Vijver Pieter | |  | | Roothooft Julie |  | | Jans Ann | |  | | Decaluwé Kelly |  | |  | |  | | Watteeuw Sibylle |  | |  | |  | |  | | | | | | |  | | | | | | |

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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***

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

**Dossier 18662:** AMPLATZER Septal Occluder (AGA Medical Corporation)

1. **Incidents / Incidenten**

0 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 0 dossiers ont étés présentés oralement durant cette Commission d’Evaluation

54 FSCA sont soumis à la Commission / 54 FSCAs werden voorgelegd aan de Commissie

* IntelliVue MP5/5SC/5T Patient Monitor and Avalon FM20/30/40/50 Fetal/Maternal Monitor 36872 & 37796, Philips Medizin Systeme Boblingen GmbH (see fsn 16407)
* Easy Spray, Tissomat, Baxter (see fsn 17027)
* ADAPTOR,040 HUM,INTLAQUA 540 SW, 540 W/ 040 ADAPTOR, AQUAPAK 101 SW,190 ML W/040 ADAPTOR,JAPA, AQUAPAK 340 SW,340 ML W/040 ADAPTOR, AQUAPAK 340 SW,340 ML W/040 ADAPTOR,FREN, AQUAPAK 340 SW,340 ML W/040, ADAPTOR,INTL, AQUAPAK 340 SW,340 ML W/040 ADAPTOR, JAPA, AQUAPAK 340 SW,340 ML W/040B ADAPTOR,BRI, AQUAPAK 640 SW,650 ML W/040 ADAPTOR, AQUAPAK 640 SW,650 ML W/040 ADAPTOR,FREN, AQUAPAK 640 SW,650 ML W/040 ADAPTOR,INTL, AQUAPAK SW/EAU STERILE,340 ML W/ADAPTOR, AQUAPAK SW/EAU STERILE,650 ML W/ADAPTOR, HUMIDIFIER ADAPTOR 040, Teleflex medical (see fsn 17114)
* HAMILTON-G5 / S1, Hamilton Medical AG (see fsn17250)
* T2100 Treadmill, GE Medical Systems Information Technologies (see fsn 17531)
* AXIOM Aristos FX, Siemens AG Healthcare Sector (see fsn 17594)
* Intracranial monitors ( Camino and Licox), Integra Lifesciences (Ireland) Limited (see fsn 17626)
* Nasobiliary drainage catheters, Prince Medical (see fsn 17635)
* EPIQ 7, Philips Health Care (see fsn 17725)
* Philips IntelliVue Information Center iX, Philips Medical systems (see fsn 17869)
* Stryker Trauma AG (see fsn 17917
* T-Lok/Bone Marrow Biopsy Needle/ KYPHON 11 Gauge Bone Access Needle, Argon medical Devices Inc (see fsn 17994)
* GlideScope AVL Reusable GVL 2 , 3 , 5 / GlideScope GVL 3 , 4, Verathon Medical Canada (see fsn 18023)
* SureFlex Reusable Fibers, Strippers and Cleavers, American Medical Systems Inc (see fsn 18026)
* Instrument Arm Drape, Intuitive Surgical (see fsn 18140)
* Acuson S Family, Siemens Medical Solution (see fsn 18157)
* Allura Xper Systems, Philips Best (see fsn 18168)
* Skyn Natural Feel & Skyn Maximum Performance Lubri, Ansell Healthcare Europe NV (see fsn 18184)
* Talux, Vari-Flex, Vari-Flex XC, Re-Flex Shock, Re-Flex Rotate / Flex-Foot Assure, Balance Foot J, Ossur (see fsn 18192)
* Genium, Genium X3, Otto Bock Healthcare GmbH (see fsn 18196)
* AQUILION, Toshiba Medical Systems Corporation (see fsn 18230)
* DFM Transcatheter Aortic Valve System, Direct Flow Inc (see fsn 18257)
* Molnlycke Health Care AB (see fsn 18330)
* Salter Labs NebuTech Nebulizer, Salter Labs Inc. (see fsn 18383)
* Closed Suction System, Halyard Health Inc (see fsn 18437)
* Telemis-Medical, Telemis (see fsn 18527)
* Specialist 2 Intramedullary (SP2 IM) Rod 400mm Instrument, DePuy Orthopaedics (see fsn 18558)
* Thunderbeat, Olympus medical systems Corporation (see fsn 18666)
* Natrelle 133 Plus, Allergan UK Limited Marlow (see fsn 18739)
* EXETER SMALL TAPERED PIN REAMER AND EXETER LARGE TAPERED PIN REAMER, Stryker Orthopaedics (see fsn 18754)
* BD Plastipak syringe in Setsystem Kitpack, Lohmann & Rauscher Rengsdorf (see fsn 18788)
* Guiding Rod, Peter Brehm Chirurgie-Mechanik e.K. (see fsn 18808)
* Venus Versa, Venus Concept Ltd (see fsn 18838)
* InSync III Cardiac Resynchronization Therapy Pacing (CRT-P), Medtronic Inc. Minneapolis (see fsn 18851)
* Allura Xper FD, Philips Best (see fsn 18854)
* BARRIER EasyWarm, Molnlycke Health Care AB (see fsn 18855)
* VENTED PACLITAXEL SET, Baxter Healthcare SA (see fsn 18860)
* Video telescope "ENDOEYE HD II", 10 mm, 0 and 30, Olympus Winter and Ibe (see fsn 18892)
* syngo X WP (workplace), Siemens AG (see fsn 18893)
* BIRMINGHAM HIP? Modular Head 38MM~58MM Monoblock, Smith & Nephew Orthopaedics Ltd (see fsn 18894)
* Allura Xper FD20 Ceiling version only, Allura Xper FD20 OR Table, Ceiling version only, Philips Best (see fsn 18922)
* Brain Metastases, Adaptive Hybrid Surgery Analysis, BrainLAB AG (see fsn 18929)
* Flexible holding device f. sternum / thorax retra, Fehling Instruments (see fsn 18937)
* sinus-Carotid-(Conical)-RX stent, OptiMed Medizinische Instrumente GmgH (see fsn 18938)
* IOLMaster 5.5 and IOLMaster 500, Carl Zeiss Meditec AG (see fsn 18940)
* lifting Table (Water phantom carriage), IBA Dosimetry GmbH (see fsn 18973)
* Allura Xper FD10 (C) (F), Allura Xper FD10/10, Allura Xper FD10 OR Table, Allura Xper FD10/10 OR Table, Allura Xper FD20/10, Allura Xper FD20/15, Allura Xper FD20, Allura Xper FD20 OR Table, Allura Xper FD20 Biplane, Allura Xper FD20 Biplane OR Table, Allura Xper FD20/20, Allura Xper FD20/20 OR Table, Allura CV20, Cardio Vascular-Allura Centron, Philips Best (see fsn 18977)
* Evita Infinity V500, Babylog VN500, Evita V300 / with optional PS500 power supply unit, Drager Medical (see fsn 18979)
* A.L.P.S. 4.0mm Cancellous Locking Screw, Biomet Orthopaedics Inc (see fsn 18993)
* SERVO-air, Maquet Critical Care AB (see fsn 19006)
* OPTI-MIST, Unomedical Inc (see fsn 19010)
* ABSORB Bioresorbable Vascular Scaffold System, ABSORB GT1 Bioresorbable Vascular Scaffold System (see fsn 19026)
* Hemihead SS 48 M, Mathys Ltd Bettlach (see fsn 19031)
* Allura Xper/ Allura Clarity/ Allura Centron/ CV20, Philips (see fsn 19046)

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

17 études ont été présentées / 17 studies werden gepresenteerd

1. **Varia**
2. Aortic Valve Bioprothesis (TAVR & SAVR)

**La réunion s’est clôturée à 14h30**

**De vergadering wordt voor gesloten verklaard om 14h30**

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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 :*  **04/02/2016 : Salle/Zaal Horizon**  à 13h00  *om 13u00* |