|  |
| --- |
|  |
| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 02 juin 2016  Verslag van de vergadering van 02 juni 2016 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **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 | | E/V | | | Wim Verlinden |  | Thierry Descamps | |  | | | Dominique Wouters |  | Tinne Leysen | |  | | | Christine Barzin |  | Jan Saevels | |  | | | Anne-Sophie Grell |  | Alex Rijnders | |  | | | Marc Cumps | E/V | Fien Aerts | |  | | |  |  | Carole Absil | |  | | | Bart Mersseman |  | Marine Debaut | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Vandenbroucke Cédric  Dejehansart Aline |  | | Van De Vijver Pieter  Jans Ann | |  | |  |  | |  | |  | |  | | | | | | |  | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

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**

3 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 3 dossiers ont été présentés oralement durant cette Commission d’Evaluation

* Dossier 19620 (DAT) : ARTIS 230V
* Dossier 19629 (DAT) : WATCHMAN Access System
* Dossier 19972 (CCV)

51 FSCA sont soumis à la Commission / 51 FSCAs werden voorgelegd aan de Commissie

* Allura Xper, Philips Medical Systems BV (see fsn 17292)
* Heating unit, pad, water, system / Heater-Cooler System 1T/3T, Sorin Group Deutschland (see fsn 17889)
* Femoral stem COMOR TAILLE 9 (Ref. COMO9) + CERAM CONCEPT TITANIUM Modular neck (Ref. C0007, C0008), Ceramconcept (see fsn 18220)
* Puritan Bennett 980 Ventilator, Covidien Healthcare (see fsn 18261)
* Insufflationsschlauch Silikon, Xion GmbH (see fsn 18364)
* Allura Xper Systems, Philips Best (see fsn 18616)
* PFNA, PFNA-II, DFN, & PFN Nails, PFNA & PFNA-II Blades, and PFNA & PFNA-II End Cap Extensions, Synthes GmbH (see fsn 19169)
* C-flex, Sulcoflex, Superflex and T-flex Aspheric, Rayner Intraocular Lenses Limited (see fsn 19237)
* Quadrox-iD adult/small adult, Maquet Cardiopulmonary AG (see fsn 19278)
* Enteral feeding sets, Nestec SA (see fsn 19285)
* Oxylog 3000, Oxylog 3000 plus and Oxylog 2000 plus, Drager Medical (see fsn 19320)
* Surfix Alpha screw and locking screw titanium dia. 2.7mm L.24mm – Sterile, Surfix Alpha screw and locking screw titanium dia. 2.7mm L.20mm – Sterile, Newdael SAS (see fsn 19569)
* InterStim Test Stimulation Lead Kit, Medtronic Inc. Minneapolis (see fsn 19577)
* XEN 45 Gel Stent, AqueSys Inc. (see fsn 19595)
* Reveal LINQ Insertable Cardiac Monitor (see fsn 19598)
* ProcedurePak kits and trays containing umbilical clamps, Molnlycke Health Care AB (see fsn 19601)
* Emprint Percutaneous Antenna -Thermosphere? Tech, Covidien Healthcare (see fsn 19613)
* Juno DRF, Villa Sistemi Medicali SPA (see fsn 19672)
* Monopolar Instruments & Bipolar Instrument Handle, Integra MicroFrance SAS (see fsn 19678)
* X-ray system, diagnostic, computed tomography, GE Medical Systems Information Technologies (see fsn 19679)
* Artis Zee floor, Siemens AG (see fsn 19681)
* Virage OCT Spinal Fixation System, Zimmer (see fsn 19686)
* TOPAZ Microdebrider, ArthroCare Corporation (see fsn 19693)
* FRED Easyport, Schiller AG (see fsn 19722)
* Arctic sun Temperature Management System, Medivance (see fsn 19726)
* Artis zee, Siemens AG (see fsn 19754)
* MatrixMANDIBLE Lock Screw Diameter 2.0 mm Self-Tapping Length 8 mm Titanium Alloy (TAN), Pack of 1 Unit in Clip, Sterile, Synthes GmbH (see fsn 19765)
* Vaxcel PICC, Xcela PICC & BioFlo PICC, Navilyst (see fsn 19813)
* Extended Brilliance WorkSpace NM 2.0, Philips Healthcare Ohio (see fsn 19815)
* Integra 3, Research Instruments Limited (see fsn 19825)
* Tete femorale HAGAP Inox 22,2 12/14 medium neck 0, Evolutis (see fsn 19844)
* Aisys CS2, Datex Ohmeda Inc (see fsn 19859)
* Lil' Angel Halo Vest, Ossur (see fsn 19867)
* Medtronic CareLink Monitor (Patient Home Monitor), Medtronic (see fsn 19882)
* Somatom Force ; SOMATOM FORCE Mat., Siemens AG (see fsn 19904)
* Ellipse VR/DR Implantable Cardioverter Defibrillators (ICDs), St Jude Medical (see fsn 19912)
* Hitachi Aloka ; ARIETTA 60, ARIETTA 70, Hitachi Aloka Medical Ltd (see fsn 19916)
* CDI Blood Parameter Monitoring System 500, BPM, Terumo Cardiovascular Systems (see fsn 19941)
* Surefuser +, Nipro Corporation (see fsn 19997)
* CATSmart, Fresenius Kabi Medical Care AB (see fsn 20006)
* Beacon Tip Angiographic Catheters, Cook Incorporated (see fsn 20009)
* Procedure packs - The Beacon tip catheters, manufactured by Cook Incorporated, William Cook Europe Aps (see fsn 20010)
* Zelos PTA-Balloon Catheter, OptiMed Medizinische Instrumente GmbH (see fsn 20011)
* Catheters, Salpingography, Catheters, Salpingography, Catheter, Ureteral, General & Plastic Surgery, Cook Incorporated (see fsn 20018)
* Allura Xper FD10 (C) (F),

Allura Xper FD10/10Allura 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

Integris systems: INTEGRIS H3000, INTEGRIS HM3000, INTEGRIS BN/BV3000, INTEGRIS BV3000 MONO, INTEGRIS BH3000, INTEGRIS V3000, INTEGRIS V3000, INTEGRIS V3000, INTEGRIS H5000, INTEGRIS BH5000, INTEGRIS V5000, INTEGRIS BV5000, INTEGRIS Allura 9 (biplane), INTEGRIS CV, INTEGRIS Allura 15-12 (mono), INTEGRIS Allura 15-12 (biplane), Philips Best (see fsn 20021)

* Battery Pack Used with the Capnostream 20 and Capnostream 20p Patient Monitor, Oridion Medical 1987 Ltd. (see fsn 20022)
* TRILLY FULL COATED STERILE, TRILLY FULL COATED STERILE, INFANT pACK W!TRYLLY ONCO D, TRILLY STERILE, TRILLY FULL COATED STERILE, TRILLY A.F.INTEGR.COATED STER., Eurosets (see fsn 20041)
* ExacTrac Vero, BrainLAB AG (see fsn 20070)
* Redcord Axis, Redcord AS (see fsn 20074)
* Mobile Diagnost wDR, Philips Medical Systems DMC GmbH (see fsn 20075)
* SpeediCath Compact Eve, CH 12, Coloplast A/S (see fsn 20078)

1. Etudes cliniques / Klinische studies

3 études ont été présentées / 3 studies warden gepresenteerd

1. Varia
   1. Namostim
   2. Terrafor ventre-plat
   3. Prochaines réunions : Les commissions de Juillet et Août se feront par emails sauf s’il devait y avoir une urgence ou un problème grave

**La réunion s’est clôturée à 14h00**

**De vergadering wordt voor gesloten verklaard om 14h00**

|  |
| --- |
| 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 :*  **01/09/2016 : Salle/Zaal Horizon**  à 13h00  *om 13u00* |