|  |
| --- |
|  |
| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 06 Février 2014  Verslag van de vergadering van 06 Februari 2014 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **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 | | E / V | | | Awatif Jebari | E / V | Emmanuelle Gay | | E / V | | | 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 | | 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 | | P / A | | | Anne-Sophie Grell |  | Alex Rijnders | |  | | | Marc Cumps | P / A | Fien Aerts | |  | | |  |  | Carole Absil E / V | |  | | | Bart Mersseman | P / A | Marine Debaut E / V | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Vanackere Sébastien | Cédric Vandenbroucke | | Eglem Steve | |  | | Julie Roothooft | Lambot Damien | | Dejehansart Aline | |  | | Meulders Frédérique | Luchian Christina | | Dumonceau Caroline | |  | |  | | | | | | |  | | | | | | |  | | | | | | |  | | | | | | |

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

Le président ouvre la réunion à 13h00. Le quorum n’est pas atteint.

*De voorzitter opent de vergadering om 13u00. 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***

*Nihil*

1. **Suivi des incidents/ *Opvolging van de incidenten***

*Nihil*

1. **Incidents**

5 dossiers ont été présentés oralement durant cette séance de la Commission d’Evaluation / 5 dossiers werden mondeling voorgesteld tijdens deze vergadering van de Evaluatiecommissie.

86 FSCA soumis à la Commission / 86 FSCAs werden voorgelegd aan de Commissie :

* ACUITY Universal Cutter
* BD Visitec TM High Viscosity Injector
* GENius Multi-Channel RF generator
* Eclipse Treatment Planning System (see fsn 9958)
* Corpuls 3
* Eclipse Treatment Planning System (see fsn 10664)
* Clinac, Trilogy, Trilogy Tx, and Novalis Tx linear accelerators
* Plum A+3 with Hospira MedNet Software and Plum A+ Driver
* Allura Xper
* NANOS Neck Preserving Hip Stem
* Invacare FDX
* Plum A+ (see fsn 12604)
* HL-30
* Plum A+ Family of Infusers
* Artis zeego (see fsn 12834)
* AXIOM ARTIS, ARTIS ZEE, ARTIS ZEEGO (see fsn 12859)
* Sigma Delta Vaporizer (see fsn 13022)
* OtisMed ShapeMatch Cutting Guides (see fsn 13092)
* NIM Flex EMG Endotracheal Tube (see fsn 13204)
* LIGACLIP? 10 mm M/L Endoscopic Rotating, Multiple Clip Appliers and FLEX TRAY Procedure Delivery System Laparoscopic Cholecystectomy Pack (see fsn 13257)
* Laparoscopic Cholecystectomy Pack, Laparoscopic holecystectomy (BASX) Pack, Laparoscopic Urology Pack, Laparoscopic Colon Pack

Laparoscopic Gastric Bypass Pack, Laparoscopic Nephrectomy Pack

Laparoscopic Sleeve Resection Pack

* Codman Certas Programmable Valve (see fsn 13291)
* DV engineering platforms
* Dynamic Multileaf Collimator (see fsn 13301)
* ECHELON 60 ENDOPATH STAPLER Endoscopic Linear Cutter Reload Black 4.4 mm, 6 rows (see fsn 13319)
* BD Vacutainer Multiple Sample Luer Adaptor (see fsn 13334)
* BioMend Absorbable Collagen Membrane, BioMend Extend Absorbable Collagen Membrane, CollaCote Absorbable Collagen Wound Dressing for Dental Surgery, CollaPlug Absorbable Collagen Wound Dressing for Dental Surgery, CollaTape Absorbable Collagen Wound Dressing for Dental Surgery
* Sutureless Connector (SC) Intrathecal Catheters
* HeartWare Ventricular Assist System
* CO-pilot Attendant Control P+ and R-net (see fsn 13401)
* Maquet HLS cannula with Bioline coating
* Paradigm Reservoirs
* BD Vacutainer Flashback Blood Collection Needle (see fsn 13562)
* Zimmer Free-Lock Femoral Fixation System, VERSA-FX Femoral Fixation System and VERSA-FX II Femoral Fixation System (see fsn 13664)
* GE Centricity PACS
* V60 Ventilator (see fsn 13700)
* 3M Scotchcast Wet or Dry Cast Padding
* Aequalis Reversed II / Reversed Fracture Impactor
* DMLC (see fsn 13778)
* Administration sets (infusion pump, Intravenous & Blood transfusion
* EOLE 3 XLS
* Advantx, Innova 2000, Innova 2100IQ, Innova 3100, Innova 3100IQ, Innova 4100, Innova 4100IQ Cardiovascular X-ray imaging systems (see fsn 13857)
* Application Instrument for Sternal ZipFix
* THERMOCOOL"SMARTTouCH Catheter
* TRACOE twist
* AXIOM ARTIS (see fsn 13919)
* INFUSOR, FOLFUSOR and INTERMATE Portable Elastomeric Infusion Systems (see fsn 13944)
* 200 mm EverFlex Self-expanding Peripheral Stent with Entrust? Delivery System (see fsn 13951)
* GENERAL PURPOSE TEMPERATURE PROBE (see fsn 13965)
* Star Excimer Laser System (see fsn 13984)
* Helical Blade for TFN, Titanium Alloy (see fsn 14017)
* NC Sprinter RX Balloon Dilatation Catheter (see fsn 14028)
* Blutschlauchsystem V 95.2971
* GSI Viewer
* Gemstar Infusion System 13000, 13100, 13150, 13086, 13087, 13088
* OPTEASE Retrievable Vena Cava Filter
* LifeStent Vascular Stent System
* OEC Brivo 865 Plus, OEC Brivo 785 Essential, OEC Brivo 715 Prime (see fsn 14101)
* Implant Holder for SynFix-LR
* Trima Accel System (see fsn 14128)
* Cougar, Zinger, Thunder, ProVia
* STERRAD 100NX
* Lifeshield, Latex-Free, Non-DEHP, Primary Plumset, 15 Micron Filter In Sight Chamber, Prepierced Y-Site, 272 CM
* RayStation
* Engstrom Ventilator, Aespire View, Aisys and Avance, Avance CS2, Amingo (Germany only) anesthesia machines (see fsn 14177)
* Discovery NM/CT 670, Discovery NM 630, Optima NM/CT 640, Brivo NM 615
* SynReam Medullary Reamer Head 8.5 mm
* Inzil 12/15mm Retrieval System
* Teflon Tube, sterile T2 Humerus
* Brivo CT 315, Brivo CT 325, Brivo CT 385, Optima CT 520, Optima CT 540
* Pari Sole N, Pari Sole N Tracheo 025
* Tibial resection Guide (see fsn 14237)
* E.cam/Symbia E
* ADAC ARGUS, ADAC CIRRUS
* da Vinci S Surgical System, da Vinci Si Surgical System, da Vinci Si-e Surgical System (see fsn 14280)
* Surg. drill guide, reusable; Ortho. reamer guide
* Sleep.safe Set (-Plus; -Plus JP version; -Paed) (see fsn 14323)
* Toptex lite X-ray detectable Laparotomy Swab
* Portex Arterial Blood Sampling Line Draw Syringes (see fsn 14331)
* Twister Plus rotatable retrieval device
* Puritan Bennett 840 Ventilator (see fsn 14385)
* Biolox Delta Trinity Modular heads
* Medrad Veris
* SERVO-U, SERVO-n
* Synergy XVI
* Post-dilation catheter (see fsn 14545)
* NanoClave Needlefree Connector (see fsn 14555)

1. **Etudes cliniques / *Klinische studie***

17 études ont été présentées / 17 studies werden gepresenteerd

1. **Varia**

Terumo: Dossier 12723 (Terumo Advanced Perfusion System 1)

La réunion s’est clôturée à 14h50  
De vergadering wordt voor gesloten verklaard om 14u50.

|  |
| --- |
| 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 :*  **13/03/2014 : Salle/Zaal 06D288**  à 13h00  *om 13u00* |