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| **Commission d’évaluation des dispositifs médicaux****Evaluatiecommissie voor medische hulpmiddelen**Compte-rendu de la réunion du 13 novembre 2014Verslag van de vergadering van 13 november 2014 |

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| **Liste de présence – Aanwezigheidslijst** |
| **Membres Effectifs****Effectieve leden** | P / A = Présent / AanwezigE / V = Excusé / Verontschuldigd | **Membres suppléants****Plaatsvervangende leden** | P / A = Présent / AanwezigE / 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 | 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 | E / V | Dominique Toye |  |
| Annick Verbiest |  | Philippe Noirhomme |  |
| Jacques Destiné |  | J-L Vanoverschelde |  |
| Olivier Debeir |  | Marie-José Tassignon |  |
| Wim Verlinden |  | Thierry Descamps |  |
| Dominique Wouters | E / V | Tinne Leysen |  |
| Christine Barzin |  | Jan Saevels E / V |  |
| Anne-Sophie Grell |  | Alex Rijnders |  |
| Marc Cumps  |  | Fien Aerts |  |
|  |  | Carole Absil  |  |
| Bart Mersseman  |  | Marine Debaut  |  |
| **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** |
| Vanackere Sébastien | Vandenbroucke Cédric | Jans Ann |  |
| Roothooft Julie | Decaluwé Kelly | Van de Vijver Pieter |  |
| Badisco LiesbethWatteeuw Sibylle | Eglem SteveGay Emanuelle |  |  |
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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***

Toevoeging variapunt:

* TER INFO: Aanwezigheid van mycobacteriën in een Heater cooler unit van de firma Sorin Group Deutschland
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***

1 dossier a été présenté oralement durant cette Commission d’Evaluation.

1 dossier werd mondeling gepresenteerd tijdens deze Evaluatiecommissie.

**Dossier 15561:** ThermoCool SmartTouch Uni-Directional Navigation Catheter (Biosense Webster Inc)

1. **Incidents**

2 dossiers ont été présenté oralement durant cette Commission d’Evaluation.

2 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie.

**Dossier 15801:** PROMUS Element Everolimus Coronary Stent System (BOSTON Scientific Corporation)

**Dossier 16211:** EDS III Ventricular cerebrospinal fluid drainage kit (Codman & Shurtleff, Inc.)

69 FSCA sont soumis à la Commission / 69 FSCAs werden voorgelegd aan de Commissie.

* QUADROX-i, all sizes and membrane types (see fsn 11576)
* Coherence RT Therapist (see fsn 12976)
* Instrument tray (see fsn 13688)
* u-HEAD / SBirHead and uHead Sterile Packaged Stems (see fsn 13932)
* IntelliSpace PACS 4.x (see fsn 14124)
* IN.PACT Amphirion drug-eliting PTA balloon catheter (see fsn 14250)
* Sterile injection syringe for single use – Luer (no fsn available)
* BD Plastipak 50ML Luer Lok Syringue Sterile (see fsn 14614)
* Zimmer Segmental System Polyethylene Insert-Size B & Size C (see fsn 14654)
* Somatom Definition, AS, Edge, Flash (see fsn 14672)
* Likamed GmbH (see fsn 14771)
* Leads used for Medtronic Spinal Cord Stimulation (SCS) Therapy (see fsn 14848)
* Group 1:Prontoprime 5UI/ml, Prontoprime 2.5UI/ml / Sterile priming solution with heparin

Group 2:NaCl 0,9% Priming CF emol 2000ml, NaCl 0,9% x Priming / Sterile Priming Solutions (see fsn 14875)

* Reveos 3 Component Blood Bag Set (see fsn 14956)
* MAQUET PowerLED, MAQUET H LED Series (see fsn 14985)
* ACUSON P300 with PA230 Transducer (see fsn 15057)
* Paradigm Insulin Infusion Pump (see fsn 15066)
* S\_ROM Noiles Rotating Hinge Femur with Pin (see fsn 15072)
* Guide Wire diameter 3.2 mm, length 400 mm (see fsn 15214)
* HeartStart XL+ Defibrillator/Monitor (see fsn 15235)
* Peripheral Access Arterial / Femoral Arterial Cannulas (37695) (see fsn 15283)
* PENTAX Ultrasound UPPER GI Video Scopes (see fsn 15293)
* SynchroMed Refill Kit (see fsn 15316)
* D2RS System, DX-D 800, XCELLENCE DYNAMIC, D2-S0RF (see fsn 15335)
* AXIOM Luminos dRF (see fsn 15340)
* HAMILTON-G5 / S1 (see fsn 15351)
* RayStation (see fsn 15379)
* Single-Chamber External Pulse Genarator (see fsn 15394)
* Gynecare Laparoscopic Morcellator (Also known as GYNECARE X-Tract Tissue Morcellator);Gynecare Laparoscopic Motor Drive Unit (MDU); GYNECARE MORCELLEXTM TissueMorcellator / Morcellex Sigma Tissue Morcellator; MORCELLEX Sigma Generator

Model: Gynecare Laparoscopic Morcellator (Also known as GYNECARE X-Tract Tissue Morcellator); Gynecare Laparoscopic Motor Drive Unit (MDU); GYNECARE MORCELLEXTM Tissue Morcellator / Morcellex Sigma Tissue Morcellator; MORCELLEX Sigma Generator (no fsn available)

* HeartWare Ventricular Assist System (see fsn 15461)
* Guide Wire diameter 3.2 mm, length 400 mm (see fsn 15580)
* Unisense FertilitiTech A/S (see fsn 15598)
* AGFA Digital Radiography X-Ray system DX-D 100 (see fsn 15600)
* Sagittal Saw Blades for Arthrex 600 (see fsn 15610)
* Anspach Attachments and Handpieces (see fsn 15638)
* PB840 Ventilator (see fsn 15640)
* SYNGO RT DOSIMETRIST (see fsn 15650)
* syngo RT Therapist / syngo RT Oncologist (see fsn 15735)
* Pasteur Pipets (see fsn 15777)
* Molnlycke Health Care ProcedurePak Cysto I/A set Single OD 20Ch ID 14Ch 200cm Drip chamber Sil. Tube + LL Irrigation set double spike OD 21Ch 200cm Soft drip chber 2 clamps Sil. Uro I/A double set 240cm Drip chamber Sil. Tube Irrigation set dbl.spike OD 21CH 250cm Soft drip chamber Clamps Sil. tube 10cm. Lap. suction/irrigation set single spike Removable cannula OD 5mm 44cm Insufflation Filter Set with 3.1m tubing

Irrigation set double spike OD 30Ch 255cm 3 clamps Sil. tube 15cm (no fsn available)

* Instruments with flexible shafts (see FSN) / RM Classic Reaming shaft flex Shaft flex. for RM Classic cup, RM Pressfit cup, CCE roof ring 3.14.545 (see fsn 15803)
* Codman Certas Programmable Valve (see fsn 15863)
* Allura Xper Systems (see fsn 15887)
* AdVance XP Male Sling System (see fsn 15901)
* EVIS EXERA II VIDEODUODENOSCOPE TJF-Q180V (see fsn 15908)
* AFFINITY FOUR BIRTHING BED (see fsn 15913)
* Ultrafilter U 9000 (no fsn available)
* Belluno Krankenpflegebett (see fsn 15924)
* Integra" LED Battery Charger, Single Bay (see fsn 15932)
* E.cam and Symbia E collimator carts (see fsn 15940)
* Calcibon (see fsn 15949)
* QLAB (see fsn 15979)
* TEGRIS OR TABLE CONTROL (see fsn 15999)
* Gender Solutions Patello-Femoral Joint System (see fsn 16054)
* S Series / Sequoia / X700 / X300PE / Antares / Cypress / CV70 (see fsn 16096)
* CoStorSol-1000mL Belzer UW Cold Storage Solution (see fsn 16100)
* Belzer UW Cold Storage Solution (see fsn 16101)
* 840 Ventilator (see fsn 16108)
* Follicle Aspiration Set/Oocyte Retrieval (see fsn 16154)
* MobileDiagnost wDR (see fsn 16161)
* da Vinci Xi Surgical System (see fsn 16183)
* HUDSON RCI (see fsn 16194)
* Specular Microscope (see fsn 16196)
* Piezomed (see fsn 16198)
* CARESCAPE Respiratory Modules (see fsn 16201)
* Portico Transcatheter Aortic Heart Valve System (see fsn 16202)
* EDS III (see fsn 16211)
* Cognis CRT-D, Teligen VR ICD and Teligen DR ICD (no fsn available)
* GMK lntramedullary Extension Rod 100 mm (see fsn 16227)
* Ovation Prime Abdominal Stent Graft System (see fsn 16229)
* ECHELON 60 ENDOPATH STAPLER Endoscopic Linear Cutter Reload (see fsn 16230)
* Peripherally Inserted Central Catheter (PICC) kits (see fsn 16335)
1. **Etudes cliniques / *Klinische studie***

9 études ont été présentées / 9 studies werden gepresenteerd

1. **Varia**
2. Publicité des dispositifs médicaux

Dit werd besproken op de Evaluatiecommisie van 04 september 2014. Ce point a été discuté à la réunion du 4 septembre 2014.

1. TER INFO: Aanwezigheid van mycobacteriën in een Heater cooler unit van de firma Sorin Group Deutschland
2. De evaluatiecommissie van januari 2015, zal niet plaats vinden op de gebruikelijke 1ste donderdag van de maand. De 1ste donderdag van januari is 01/01/2015 en dit is een officiële feestdag. De Evaluatiecommissie van januari zal dus plaats vinden op 08 januari 2015.

La Commisison d’Evaluation de janvier aura lieu le jeudi 8 janvier 2015 étant donné que le premier jeudi de janvier est le 1er.

La réunion s’est clôturée à 14h30
De vergadering wordt voor gesloten verklaard om 14u30.

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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 :***04/12/2014 : Salle/Zaal 06D288** à 13h00*om 13u00* |