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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 04 Septembre 2014  Verslag van de vergadering van 04 September 2014 |

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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 | 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 | E / V | Tinne Leysen | |  | | | Christine Barzin |  | Jan Saevels P / A | |  | | | Anne-Sophie Grell |  | Alex Rijnders | |  | | | Marc Cumps |  | Fien Aerts | |  | | |  |  | Carole Absil E / V | |  | | | Bart Mersseman P / A |  | Marine Debaut E / V | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Vanackere Sébastien | Vandenbroucke Cédric | | Dejehansart Aline | | Luchian Cristina | | Julie Roothooft | Decaluwé Kelly | | Roisin Thierry | | Jans Ann | | Badisco Liesbeth | Driesmans Christophe | | De Smedt Ief | | Van De Vijver Pieter | |  | | | | | | |  | | | | | | |  | | | | | | |  | | | | | | |

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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***

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***

1 dossier a été représenté oralement durant cette Commission d’Evaluation. 1 dossier werdt mondeling gepresenteerd tijdens de zitting van de evaluatiecommissie

**Dossier 14222:** Lumax 540 VR-T (Biotronik Gmbh)

1. **Incidents**

1 dossier a été présenté oralement durant cette Commission d’Evaluation. 1 dossier werdt mondeling gepresenteerd tijdens de zitting van de evaluatiecommissie

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

91 FSCA ont été soumis à la Commission. 91 FSCAs werden voorgelegd aan de Commissie.

Dental unit (XO Operation Lamp) (see fsn 10439)

Instrument Arm Drape IS2000 and IS3000 (see fsn 11874)

Sabina and Capella Sit-to-Stand mobile lifts (see fsn 12177)

* LifeCare PCA Plus II (1950), LifeCare PCA 3 (12384), LifeCare PCA / LifeCare PCA with MedNet (20709),LifeCare PCA TM Infusion System (0F782) (see fsn 12966)

OPTEASE Retrievable Vena Cava Filter (see fsn 12989)

Maximo, pediatric bed (see fsn 13110)

Trima Accel System (see fsn 13280)

Patterson Walking Crutches (see fsn 13396)

PLATINUM (see fsn 13642)

* VA-LCP Anterolateral Distal Tibial Plate 2.7/3.5 / MultiLoc Screw 4.5 mm, length 30 mm (see fsn 13797)

AQUATEC Ocean VIP / Ocean VIP, Ocean VIP XL, Ocean Dual VIP and Ocean E-VIP (see fsn 13952)

A-dec 311 Chair, A-dec 361 Support Centre, A-dec light post (part no. 28.1949.00), A-dec 7285 Radius Cuspidor (see fsn 14025)

Heart-Lung Machine HL30 (see fsn 14073)

GemStar Desk Top Power Supply, 3VDC (see fsn 14150)

ARTIS ZEE CEILING (see fsn 14294)

Excelsior / GDC / Neuroform EZ / Compliant (see fsn 14350)

Optima XR220amx, Optima XR200amx with Digital Upgrade (see fsn 14413)

PET Discovery 610 and PET Discovery 710 (FMI 13715), PET Discovery 600 and Discovery 690 (FMI 13716) (see fsn 14491)

ADEPT Hip Resurfacing System (see fsn 14524)

15 L Cycler Drainage Bag (see fsn 14538)

SynReam Medullary Reamer Head 8.5 mm (see fsn 14572)

CPT - Custom procedure trays (see fsn 14742)

ELS 200 ml syringe and syringe sets (ELS) (see fsn 14744)

MedtroniC@ Select 3D and Select CAP Arterial Cannula (see fsn 14745)

corpuls3 - Defibrillator/Pacer unit SLIM (see fsn 14763)

Impax RIS (see fsn 14791)

Giraffe Stand Alone Infant Resuscitation System (StAR); Giraffe Warmer with Resuscitation System; Panda Warmer with Resuscitation System; Resuscitation System upgrade kits; Panda Freestanding with Resuscitation System (see fsn 14802)

Giraffe Stand Alone Infant Resuscitation System (StAR) with Blender; Giraffe Warmer Integrated Resuscitation system with Blender; Panda Warmer Integrated Resuscitation system with Blender; Panda Freestanding Warmer Integrated Resuscitation system with Blender; Resuscitation System field upgrade kits with Blender (see fsn 14809)

aycan OsiriX (see fsn 14815)

FreeStyle Mini and FreeStyle Blood Glucose Monitoring System (see fsn 14836)

HeartMate II LVAS System Controller (see fsn 14969)

Devapor (see fsn 14974)

Set of preparation / administration of chemotherapy (see fsn 15012)

STANDOP VOLISTA (see fsn 15016)

PLEGIOX Cardioplegia Heat Exchanger (see fsn 15025)

Weck Vista Universal Laparoscopic Port, Size 5/10mmx100mm, 10mm; Weck Vista Cannula-only 5/10 mm; Weck Vista Optical Bladeless Laparoscopic Access Port 5/10 mm; Weck Vista Universal Cannula; Weck Vista Universal Laparoscopic Port, Size 5/10/12 mmx100mm; Weck Vista Universal Laparoscopic Port, Size 5/10/12 mmx125mm, 12mm; Weck Vista Cannula-only 5/10/12 mm; Weck Vista Optical Bladeless Laparoscopic Access Port 5/10/12 mm; Weck Vista Universal Cannula 5/10/12MM X 100MM; Weck Vista UNIVERSAL CONE OPEN ACCESS 5/10; Weck Vista Universal Balloon Open Access Port Standard Length (70mm) 5/10; Weck Vista Universal Balloon Open Access Port Long Length (100mm) 5/10; Weck Vista Universal Balloon Open Access Port Short Length (53mm) 5/10/12; Weck Vista Universal Balloon Open Access Port Standard Length (70mm) 5/10/12; Weck Vista Universal Balloon Open Access Port Long Length (100mm) (see fsn 15036)

Biomedics 1 Day (55%) Toric (see fsn 15079)

HomeChoice Automated PD System and HomeChoice PRO Automated PD System (see fsn 15080)

SynPlug and OptiPlug (see fsn 15110)

Diamond Cutter (see fsn 15132)

Terumo Advanced Perfusion System 1 (see fsn 15134)

Interpulse Handpiece (see fsn 15143)

Symbia T and Symbia T2 SPECT/CT systems (see fsn 15152)

STIMPOD (see fsn 15173 & 15174)

Ring Applicator Set (45, 60,90) (see fsn 15176)

THERMOCOOL SF NAV CATHETERS (see fsn 15198)

da Vinci Si Single Site Reusable Accessory (see fsn 15211)

Cavafix Certo, Cavafix Certodyn (see fsn 15213)

Colleague pump (see fsn 15216)

PED, ARD (see fsn 15231)

Fraxel DUAL 1550/1927 Laser System (see fsn 15234)

Artis zeego (see fsn 15258)

Infant Nasal CPAP Prongs (see fsn 15266)

Soft tissue gauge 6mm (see fsn 15271)

AXIOM Artis ; diverse - various / diverse – various (see fsn 15274)

Otesus (see fsn 15277)

ACUSON X700 (see fsn 15326)

HexaPOD evo RT System (see fsn 15342)

12 In strument Sterilization Tray (see fsn 15400)

Vivid E9 (see fsn 15406)

Wortie (Wrattenverwijderaar / Produits antiverrues) (see fsn 15409)

Accessory Extension Device / ALPHAMAQUET (see fsbn 15424)

syngo Workflow MLR (see fsn 15426)

Argus 717 V (see fsn 15459)

ELECTROSURGICAL DISPERSIVE ELECTRODE, MACROLYTE, P (see fsn 15460)

NOxBOXi (see fsn 15488)

Lantis Commander oder Lantis System (see fsn 15503)

NxStage PureFlow SL SAK (see fsn 15513)

Acuson S Family (see fsn 15539)

ReNew Fenestrated Grasper Forceps Tips (see fsn 15544)

seleXys DS Pfanne 48 unzem. (see fsn 15550)

PARACHUTE Guide Catheter, 14Fr (see fsn 15553)

Mentor Gel Sizer (see fsn 15563)

SUTUREFIX Ultra Anchors (see fsn 15583)

CT Expres 3D contrast media injection system (see fsn 15602)

FUJIFILM Digital Mammography System AMULET (see fsn 15608)

Bard Hydrogel Coated Prostatic Catheter (see fsn 15630)

Drill Bit with stop (see fsn 15631)

EXCOR Blood pump (see fsn 15644)

PRIMUS ONCOR ARTISTE MEVATRON (see fsn 15673)

Basin Liner (see fsn 15701)

Cutting Accessories (see fsn 15716)

Basin Liner (manufactured by Microtek), component of Custom Procedure Trays (by Kimberley-Clark) (see fsn 15725)

EndoWrist Large Clip Applier Instrument (see fsn 15738)

CARESCAPE Monitor B650 (see fsn 15759)

ENDOTAK RELIANCE? SG-4 SITE (see fsn 15763)

Application Instrument for Sternal ZipFix (see fsn 15787)

The Belmont Hyperthermia Pump (see fsn 15789)

Axium Implantable Lead Kit (see fsn 15831)

KODAK (see fsn 15837)

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

Information aux membres : deux experts dispositifs médicaux vont à l’avenir pouvoir rendre des rapports de qualité sur les études cliniques.

9 études ont été présentées. 9 studies werden gepresenteerd.

1. **Varia**
2. Publicité des dispositifs médicaux / Publiciteit voor medische hulpmiddelen

Monsieur Roisin a présenté à la Commission une nouvelle tâche supplémentaire (dont la date d’exécution n’a pas encore été arrêtée) consistant à bien « contrôler » la publicité des dispositifs médicaux mais pas celle des cas « borderline ».

Une discussion a été ouverte sur les critères objectifs sur lesquels la commission pourrait s’appuyer. Nous allons interroger nos collègues du département « médicaments » pour voir comment ça se passe chez eux.

Mijnheer Roisin heeft de Commissie een nieuwe bijkomende taak waarvoor de startdatum nog niet gekend is voorgesteld, namelijk de controle op publiciteit van medische hulpmiddelen, uitgezonderd «borderline» producten.

Hierop volgend werd gediscussieerd over objectieve criteria waarop de commissie zou kunnen steunen. Wij zullen nagaan hoe onze collega’s van het departement «geneesmiddelen» dit aanpakken.

1. Cyberonics

Nous avons rencontré la firme qui a émis le souhait de faire des PSR (Periodic Summary Report) pour regrouper les notifications d’incidents de dans des cas bien précis. Aucune objection de la commission à priori.

Wij hebben vertegenwoordigers van de firma ontmoet om de eventuele introductie van PSRs (Periodic Summary Reports) te bediscussiëren. Cyberonics wenst hiermee gespecificeerde incident meldingen te groeperen. Geen bezwaren van de Commissie.

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

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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 :*  **02/10/2014 : Salle/Zaal 06D288**  à 13h00  *om 13u00* |