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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 14 avril 2016  Verslag van de vergadering van 14 april 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 |  | Emmanuelle Gay | | P/A | | | Maries Merken |  | Rita Cornélis | |  | | | Guibert Crèvecoeur |  | Jean-Claude Mignolet | |  | | | Isabelle De Pau ad it. Tom Clarijs |  | 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 | |  | | | Anne-Sophie Grell |  | Alex Rijnders | |  | | | Marc Cumps |  | Fien Aerts | |  | | |  |  | Carole Absil | |  | | | Bart Mersseman |  | Marine Debaut | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Decaluwe Kelly |  | | Van De Vijver Pieter | |  | | Vandenbroucke Cédric  Lambot Damien  Dejehansart Aline  Roothooft Julie  Watteeuw Sibylle |  | | Jans Ann | |  | |  | | | | | | |  | | | | | | |

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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***

0 dossier werd mondeling gepresenteerd tijdens deze Evaluatiecommissie / 0dossier ont été présentés oralement durant cette Commission d’Evaluation

1. **Incidents / Incidenten**

5 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 5 dossiers ont été présentés oralement durant cette Commission d’Evaluation

* Dossier 18537 FRESENIUS KABI Medicale Care AG – FX Cordiax 800
* Dossier 18839 SORIN Group Italia srl – valve cardiaque aortique biologique Perceval-S
* Dossier 19434 & 19435 : matela quattro overlay et matelas quattro plus
* Dossier 19499: AGA MEDICAL – Amplatzer amulet

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

* Medrad Continuum MR Infusion System, Bayer Medical Care Inc. (see fsn 15332)
* MOSAIQ, IMPAC Medical Systems Inc. (see fsn 16505)
* Perfect O2, Perfect O2V, Platinum S, Platinum 9, Invacare Rehabilitations Equipment (Suzhou) Co. Ltd (see fsn 16618)
* Brilliance CT 16 Air, 64, Big Bore, iCT, iCT SP, Ingenuity CT, Ingenuity Core, Ingenuity Core128, Ingenuity Flex, Philips Healthcare Ohiio (see fsn 16864)
* Biolox Delta Head, Durasul, Zimmer GmbH (see fsn 16957)
* Inserter f/TEN, Synthes GmbH (see fsn 17332)
* IntraClude Intra-Aortic Occlusion Device, Edwards Lifesciences (see fsn 17789)
* NEONATAL,CUFFLESS, PHTHALATE FREE, PEDIATRIC,CUFFLESS,PHTHALATE FREE PEDIATRIC LONG,CUFFLESS,PHTHALATE FREE NEONATAL,CUFFED, PHTHALATE FREE PEDIATRIC, LONG, CUFFED, PHTHALATE FREE, Covidien Healthcare (see fsn 17796)
* Sher-I-SWIV/FO Double Swivel Connector, Sher-I-Bronch Left Sided, Sher-I-Bronch Right Sided, Sher-I-Bronch Accessory Pack (see fsn 17863)
* Molnlycke Health Care AB (see fsn 17933)
* CLEARSIGN II Amplifier, Boston Scientific Corporation (see fsn 17942)
* Contour Next, Bayer Consumer Care AG (see fsn 18303)
* Zimmer Natural Nail CM Long, Zimmer GmbH (see fsn 18511)
* Trauma Guide Wire, Zimmer Inc. (see fsn 18521)
* BodyGuard 575 PCA Infusion Pump, CME Limited (see fsn 18528)
* Patient Data Manager, BrainLAB AG (see fsn 18546)
* BD Plastipak Syringe/ BD Oral Syringe, Becton Dickinson and Company (see fsn 18556)
* SeleXys TH+ and seleXys TPS shells, Mathys Ltd Bettlach (see fsn 18564)
* Solera Screwdriver, Medtronic Navigation (see fsn 18596)
* Medtronic MiniMed 640G Insulin Pump, Medtronic Minimed (see fsn 18600)
* AMICUS CELL SEPARATOR, Fenwal Inc (see fsn 18617)
* Product Code: HARH23 Full Device Name: Harmonic ACE+7, 5 mm Diameter Shears, 23 cm Length with Advanced Hemostasis, Product Code: HARH36 Full Device Name: Harmonic ACE+7, Laparoscopic 5 mm Diameter Shears, 36 cm Length with Advanced Hemostasis Product Code: HARH45, Full Device Name: Harmonic ACE+7, Laparoscopic 5 mm Diameter Shears, 45 cm Length with Advanced Hemostasis, Ethicon Endo-Surgery (see fsn 18624)
* Procedure Packs listed in Attachment A contain Harmonic ACE+ 7 devices which are affected by a Field Safety Corrective Action (recall number HARH-2015-10).

Product Code: HARH23, Full Device Name: Harmonic ACE+7, 5 mm Diameter Shears, 23 cm Length with Advanced Hemostasis

Product Code: HARH36, Full Device Name: Harmonic ACE+7, Laparoscopic 5 mm Diameter Shears, 36 cm Length with Advanced Hemostasis

Product Code: HARH45, Full Device Name: Harmonic ACE+7, Laparoscopic 5 mm Diameter Shears, 45 cm Length with Advanced Hemostasis Affected Harmonic ACE+ 7 devices are manufactured by Ethicon Endo-Surgery LLC, Ethicon Endo-Surgery (see fsn 18625)

* ALA OCTA, Alamedics GmbH (see fsn 18832)
* Trocars, Guangzhou Weini Technology & Development Co LTD (see fsn 18867)
* GlideScope Video Laryngoscope, Verathon Incorporated (see fsn 19061)
* SynReam Medullary Reamer Head Diameter 13.5mm, Synthes GmbH (see fsn 19064)
* Powerheart G3 defibrillation electrodes, Cardiac Science Corporation (see fsn 19180)
* Nova T, Bayer Pharma AG (see fsn 19191)
* Enteral feeding sets, Nestle Cedi srl (see fsn 19235)
* h/p/cosmos treadmill, h/p/cosmos sports & medical GmbH (see fsn 19270)
* ENDOBON ROX, Biomet France SARL (see fsn 19342)
* LEGION Screw-On Hemi Stepped Tibial Wedge, Smith & Nephew usa (see fsn 19353)
* Fuhrungsstab, Peter Brehm Chirurgie-Mechanik e.K. (see fsn 19355)
* Rotatable VESA 75 / 100 adaptation, VESA 75/100 adaption with rotation, ITD GmbH (see fsn 19358)
* Super Arrow-Flex(R) Percutaneous Sheath Introducer Set, ARROW International (see fsn 19362)
* Apollo I DRF / EZ / EZ DRF; Clinodigit EVO, JunoDRF, Villa Sistemi Medicali SPA (see fsn 19365)
* LCP Distal Tibial Plate 3.5, anterolateral and Expert A2FN, Nail, Diameter 11.0mm, Right, L 360mm, Synthes GmbH (see fsn 19372)
* Uromatic Tur Administration Set, Baxter Healthcare (see fsn 19388)
* Sterile procedure trays, single use, Medline International France SAS (see fsn 19408)
* Puritan Bennett 980 Ventilator, Covidien Healthcare (see fsn 19426)
* Trinity, Alpha Konisphar Screw Cup, Corin Group PLC (see fsn 19439)
* ACP215 Automated Cell Processor, MCS+9000 Mobile Platelet Collection System MCS+8150 Multicomponent Collection System PCS2 Plasma Collection Device (see fsn 19449)
* Molnlycke Health Care AB (see fsn 19462)
* CA500, Epix0 Universal Clip Applier 3/BX, Applied Medical (see fsn 19484)
* SpeediCath Compact Eve, Coloplast A/S (see fsn 19490)
* Nellix EndoVascular Aneurysm Sealing System, Endologix Inc (see fsn 19500)
* Carestation 620 A1 / 650 A1 / 650c A1, Datex-Ohmeda Inc (see fsn 19502)
* AO 112 in 111 cannulated drill dia. 2.2/3.0mm L.32mm – STERILE, Newdael SAS (see fsn 19505)
* GlideScope Video Laryngoscope Titanium SU blades, Verathon Medical Canada (see fsn 19510)
* Hem-o-lok Auto Endo5 Medium Large Ligating Clip Applier, Teleflex medical (see fsn 19515)
* Olympus Suction Pump, Olympus Keymed UK (see fsn 19522)
* TruLight 3000, TruLight 5000, iLED, Helion, Xenion, Trumpf Medizin Systeme GmbH (see fsn 19556)
* ENT single-use suction tubes, Spiggle & Theis (see fsn 19559)
* FiberOptix Ultra 8 IAB: 8Fr 30cc, Ultra 8 IAB: 8Fr 30cc, FiberOptix Ultra 8 IAB: 8Fr 40cc, Ultra 8 IAB: 8Fr 40cc, UltraFlex IAB: 7.5Fr 30cc, UltraFlex IAB: 7.5Fr 35cc, UltraFlex IAB: 7.5Fr 40cc, RediGuard IAB: 7Fr 30cc, Percutaneous Insertion Tray, Arrow International (see fsn 19562)
* RENASYS GO Negative Pressure Wound Therapy (NPWT), Smith & Nephew (see fsn 19578)
* Cios Alpha, Siemens AG Healthcare Sector (see fsn 19589)
* Instinct Java instruments and containers, Zimmer Spine (see fsn 19619)
* SYNCHROMED II implantable pump, Medtronic Inc (see fsn 19631)
* MHI -TM2000 Linear Accelerator System/ VEROTM LINAC System/ MHI, Mitsubishi Heavy Industries (see fsn 19642)
* VERION Reference Unit, WaveLight GmbH (see fsn 19659)
* Broche 1,2 mm L100mm pointe trocart, non-sterile, Biotech Ortho, a Wright Company (see fsn 19662)
* BDYN, Biospine Implants (see fsn 19666)
* Model IS3000 da Vinci Si Surgical System - Surgeon Console, Model IS4000 da Vinci Xi Surgical System - Surgeon Console, Model IS4000 da Vinci Xi Surgical System - Patient Cart, Intuitive Surgical Inc. (see fsn 19667)
* Embase et condyle ANATOMIC HAP Taille 6, Amplitude (see fsn 19673)
* E.CAM and Symbia E family, Siemens Medical Solutions USA Inc Molecular Imaging (see fsn 19677)
* Aisys CS2, Datex-Ohmeda Inc (see fsn 19720)
* Curity/Kerlix/Vistec Sponges, Covidien Healthcare (see fsn 19725)
* REVITAN prox. spout and REVITAN prox. Cylindrical, Zimmer GmbH (see fsn 19728)

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

4 études ont été présentées / 4 studies warden gepresenteerd

1. **Varia**

* Alamedics – Ala Octa

Communications Afmps:

Le mardi 03/11/2015, les Points de Contact Matériovigilance ont été du recall des 3 lots. Les associations professionnelles ont également été averties via le même courrier.

Le mercredi 04/11/2015, les 2 hôpitaux ayant reçus le produit en 2014, ont reçu un email leur demandant de vérifier leurs stocks (et de mettre en quarantaine) et de notifier tout incident.

* Fluoron – F-Octane
* Arcadophta – Arcotane
* Mycobacterium Chimaera

La Ministre de la santé Publique a demandé au Conseil Supérieur de la Santé (CSS), de rendre un avis concernant le risque de contamination au Mycobacterium Chimaera lors de l’utilisation de Heater Cooler.

L’avis du CSS est attendu pour le mois de juin.

Au niveau Européen, la Task Force a rencontré les principaux fabricants. Nous attendons les conclusions de la Task Force ainsi que l’avis final du CSS.

* Terrafor ventre plat

**La réunion s’est clôturée à 15h00**

**De vergadering wordt voor gesloten verklaard om 15h00**

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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 :*  **12/05/2016 : Salle/Zaal 06C285**  à 13h00  *om 13u00* |