

**COMMISSION D'ÉVALUATION DES DISPOSITIFS MÉDICAUX
EVALUATIECOMMISSIE VOOR MEDISCHE HULPMIDDELEN**

COMPTE-RENDU DE LA REUNION DU 16 JUILLET 2015
VERSLAG VAN DE VERGADERING VAN 16 JULI 2015

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 + Maboge Claude	P / A	Annie Vanderlinck	
Guido Van Nooten	P/A Président	Yves Taeymans	
Hein Heidebüchel		Rik Willems	
Kristel De Vogelare		Daniel Mojet	
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	E / V
Anne-Sophie Grell		Alex Rijnders	
Marc Cumps		Fien Aerts	
		Carole Absil	E / V
Bart Mersseman		Marine Debaut	E / V

Représentants de l'AFMPS - Vertegenwoordigers van het FAGG

Vandenbroucke Cédric	Jans Ann
Decaluwé Kelly	Driesmans Christophe
Dejhansart Aline	Meulders Frédérique

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

2 **PV de la réunion précédente / Verslag van de vorige vergadering**

Approuvé / goedgekeurd

3 **Conflits d'intérêt / Belangenconflict**

Non / Neen

4 **Incidents**

4 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 4 dossiers ont été présenté oralement durant cette Commission d'Evaluation

Dossier 17577: (Allergan)

Dossier 17687: PROMUS Element (Boston Scientific) (

Dossier 17802: Intersurgical - Adult, Satin Nasal Cannula with straight prong and tube 2,1 m / Satin nasal cannula with straight prongs and tube, adult 2.1m (Intersurgical)

Dossier 17816: Fortify DR, U1.6 SJ4 ID (St Jude Medical)

55 FSCA sont soumis à la Commission / 55 FSCAs werden voorgelegd aan de Commissie

Fixed Offset Adapter, Ossur (See FSN 14201)
HeartStart MRx, Philips Medical systems (Andover) (See FSN 15227)
SmartLife™ Small / Large Aseptic Housings, Stryker Instruments-Kalamazoo (See FSN 16626)
Propaq LT / Propaq 802, Welch Allyn Inc. (See FSN 14205)
Belvita Classic, Belvita Low, FMB Care GmbH (See FSN 14780)
IntelliSpace Critical Care and Anesthesia, Philips Medical systems (Andover) (See FSN 15510)
HeartStart MRx Defibrillator Monitor, Philips Medical systems (Andover) (See FSN 14944)
Scherbak, weight 800 g, 400 g, on its own, Gebrüder Martin GmbH & Co. KG (See FSN 16098)
GE Centrality PACS, GE Healthcare Integrated IT Solutions (See FSN 15536)
Flexi-Seal CONTROL™ Fecal Management System, ConvaTec Ltd. (See FSN 15405)
HomeChoice Automated PD System and HomeChoice PRO Automated PD System, Baxter Healthcare SA (See FSN 15493)
ExacTrac Vero (versions 3.0 and higher), BrainLAB AG (See FSN 15497)
Microbore Administration sets, Q Core Medical Ltd. (See FSN 16316)
HeartStart MRx Defibrillator/Monitor, Philips Medical systems (Andover) (See FSN 14949)
HeartStart MRx Defibrillator/Monitor, Philips Medical systems (Andover) (See FSN 16743)
VYCLIC, Laboratoires pharmaceutique Vygon SA (See FSN 16634)
Arrow FiberOptix Intra-aortic Balloon (IAB), ARROW International (See FSN 17190)
Otesus, Orto Maquet (See FSN 16848)
Dual Chamber Temporary Pacemaker, Medtronic Inc. Minneapolis (See FSN 17361)
Sealing Screw Tibia UC, PETER BREHM Chirurgie-Mechanik e.K. (See FSN 17382)
Talon Grasping Device, US Endoscopy (See FSN 17440)
Replace Select Tapered TiU NP 3.5x10mm / NOBELREPLACE® Tapered Groovy RP 4.3x8mm / NobRpl Tapered Groovy 6.0mm 6x11.5mm / Replace Select Tapered TiU
Trilogy® Bone Screws/Bone Screw, self-tapping, Zimmer, Inc. (See FSN 16787)
Expel™ Drainage Catheter with Twist-Loc™ Hub: 2 Biliary Drainage Catheter and Biliary Drainage Catheter Kit: APD™ (All Purpose Drainage) Drainage Catheter and A
Engstrom Carestation, Engstrom Pro, Cart Only S/SEC, Datex-Ohmeda, Inc. (See FSN 17259)
Bard Per-Q-Cath Products, Bard Access Systems Div. (See FSN 17896)
YASARGIL Aneurysmen Clips, Gebrüder Martin GmbH & Co. KG (See FSN 16687)
da Vinci Surgical System Drapes (details see FSN), Microtek Medical Inc. (See FSN 17409)
WASSENBURG Endoscope Washer Disinfectors (EWD) WD440 / WD440 PT, WASSENBURG Medical Devices B.V. (See FSN 17422)
EVIS EXERA II VIDEODUODENOSCOPE TJF-Q180V, Olympus medical Systems Corporation (See FSN 17521)
ProAQT Sensor, PULSION MEDICAL SYSTEMS AG (See FSN 17239)
TomoTherapy Treatment System, Accuray Incorporated (See FSN 16746)
Flow-i, MAQUET Critical Care AB (See FSN 17311)
da Vinci Standard™ Surgical System, da Vinci S™ Surgical System, da Vinci Si™ Surgical System, da Vinci Si-e™ Surgical System., Intuitive Surgical (See FSN 1670
Terumo Two Part Syringe, ArcRoyal Ltd (See FSN 17453)
Artis/Evosys machines, Gambro Dasco (See FSN 16871)
KAMRA Corneal Inlay, AcuFocus Inc. (See FSN 17424)
Trestle Luxe Anterior Cervical Plating System, Alphatec Spine (See FSN 17566)
OBS Extension Kit, Medtronic Inc. (See FSN 17573)
Axor TC, Integrum AB (See FSN 17597)
Portex® Bivona® Inner Cannula for Bivona® Adult Tracheostomy Tubes, Smiths medical ASD INC (See FSN 17602)
AVEA Ventilator, CAREFUSION CORPORATION (See FSN 17621)
Condyle femoral de revision SCORE - A eimenter, Amplitude (See FSN 17622)
Multimed Light, Gasflaschenventil mit integriertem Druckregler (Ausstattungsteil der Gasflasche) / Multimed Light / Valve integrated press. regulator, Spectron Gas Co
Centricity PACS IW, GE Healthcare Integrated IT Solutions (See FSN 17679)
custom specific sets manufactured by Medline Int. several - Devon Light Glove, Medline International France SAS (See FSN 17685)
Chisel Blade, long, width 10 mm (Part Number 399.555); Chisel Blade, long, width 16 mm (Part Number 399.565); Chisel Blade, long, width 25 mm (Part Number 3
RELIANCE 4-FRONT single coil defibrillation lead, Cardiac Pacemaker Inc. (See FSN 17778)
CADD- Solis Ambulatory Infusion Pumps, SMITHS MEDICAL ASD, Inc (See FSN 17843)
Surface Applicator Set with Leipzig-style Cone, Varian Oncology Systems (USA) (See FSN 17855)
A) TARGET 360 SOFT 3.5MM X 10CMB) TARGET 360 NANO 1.5MM X 4CMD) TARGET 360 NANO 1.0MM X 3CMD) TARGET 360 SOFT 6.0MM X 15CME) TARGET 360 ULT
EV1000 NI Heart Reference Sensor, Edwards Lifesciences (See FSN 17879)
PROCISE EZ VIEW and EVAC 70 XTRA, ArthroCare Corporation (See FSN 17922)
Cios Alpha, Siemens AG Healthcare Sector - Imaging & IT Division - Magnet Resonance (See FSN 17707)
HEMOSPRAY ENDOSCOPIC HEMOSTAT, Cook Endoscopy (See FSN 15502)

5 Etudes cliniques / Klinische studies

5 études ont été présentées / 5 studies werden gepresenteerd

PUBLIC

6 Varia

1- RCT

La loi du 15/12/2013 (§ 2, Article 51) mentionne que l'avis de la commission est nécessaire pour valider la « liste implants ».

2- NU Surface

3- Strattice (LifeCell)

La réunion s'est clôturée à 14H00

De vergadering wordt voor gesloten verklaard om 14u00.

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 :

03/09/2015 : Salle/Zaal Vivaldi

à 13h00
om 13u00