

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

COMPTE-RENDU DE LA REUNION DU 02 MAI 2013
VERSLAG VAN DE VERGADERING VAN 02 MEI 2013

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	P / A	Emmanuelle Gay	E/V
Maries Merken	E / V	Rita Cornélis	
Guibert Crèvecoeur		Jean-Claude Mignolet	
Isabelle De Pau ad it. Tom Clarijs	P/A	Annie Vanderlinck	
Guido Van Nooten	P / A	Yves Taeymans	
Hein Heidebüchel		Rik Willems	
Kristel De Vogelare		Daniel Mojet	P / A
Claude Hanet		André Waleff	
Véronique Kepenne		Johan Somville	E / V
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	
Bart Mersseman	P/A	Marine Debaut	P / A

Représentants de l'AFMPS - Vertegenwoordigers van het FAGG

Vanackere Sébastien	Eglen Steve	Damien Lambot
Julie Roothoof	Sibylle Watteuw	

Le président ouvre la réunion à 13h15. Le quorum n'est pas atteint.
De voorzitter opent de vergadering om 13u15. Het quorum werd niet bereikt.

1 Ordre du jour / Dagorde

Approuvé

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

Approuvé

3 Conflits d'intérêt / Belangenconflict

Mr Mersseman (SGS) a signalé un conflit d'intérêt avec les biberons Beldico vu que SGS est leur Notify Body. Celui-ci a été noté par le secrétariat mais au vu de l'expertise de l'intéressé, il a été demandé qu'il puisse donner son avis sur le sujet sans toutefois participer au vote des actions à mettre en place

4 Suivi des incidents / Opvolging van de incidenten

- **Beldico (dossier 12816)**

5 Incidents

Pas de dossier présenté oralement durant cette réunion.

122 FSCA sont soumis à la Commission d'Evaluation / 122 FSCAs werden voorgelegd aan de Commissie

Somaton Definition AS/AS+, Siemens (See FSN 7270)
Contour SE TM Microspheres, BOSTON Scientific Corporation (See FSN 7275)
Fixation posts, Elekta (See FSN 7286)
Concerto and Virtuoso, MEDTRONIC Inc. (See FSN 7287)
Spinnaker Elite TM Flow Directed Microcatheter, BOSTON SCIENTIFIC CORP (See FSN 7288)
Durom Acetabular Cup, Zimmer GmbH (See FSN 7320)
Revolution, Sorin Group Italia (See FSN 7326)
all Power Medical Intervention products in distribution. all SurgiASSIST R Systems, devices and accessories and all Intelligent Surgical Instruments Systems, devices and accessories., Power Medical Interventions, Inc (See FSN 7333)
Paradigm Veo insulin pumps, MEDTRONIC MINIMED. (See FSN 7349)
Medena Tapered Tip, Astra Tech AB (See FSN 7354)
Bryan Cervical Disc System, Medtronic BV Heerlen (See FSN 7367)
WarmCloud Mattress, KAN MED (See FSN 7376)
Clip-a-Port, EcoPort, A.M.I (See FSN 7387)
Mölnlycke ProcedurePak R, Mölnlycke Health Care AB (See FSN 7388)
Guider Softip TM XF Guide Catheter, BOSTON Scientific Corporation (See FSN 7389)
Accessory: Connection bracket, Orto Maquet (See FSN 7390)
Clinac, C Series, Varian Medical Systems (See FSN 9163)
ETHILON* Black, ETHILON* Blue, ETHIBOND*, MERSILENE, silk, Johnson & Johnson Medical n.v. (See FSN 9165)
Cholangioscopy Access Balloon/DPOC-15, Cholangioscopy Access Balloon, G54951, 15 mm, Rx only. DPOC-20, Direct Peroral Cholangioscopy Balloon, G54951, 20 mm/17 mL, Rx Only. , Cook Endoscopy (See FSN 9174)
System 2450 R, ConMed Corporation (See FSN 9177)
Ascendra 2(TM)Delivery System, Edwards Lifesciences (See FSN 9182)
Codman® Disposable Drill Kits, Codman & Shurtleff, Inc. (See FSN 9190)
IAB-05800 Series IAB with SuperArrowFlex (Wire-reinforced) Sheath/ 5800 Series FibreOptix™ and Ultra 8 ® Catheters 30 and 40 CC IAB Catheters, ARROW International (See FSN 9194)
GE Centricity PACS Web Diagnostic Software Versions: 1.0.0.x, Healthcare Integrated IT Solutions (See FSN 9195)
Intellivue Information Center, Philips Healthcare (See FSN 9233)
SKYLIGHT Gamma Camera and Precedence Imaging System Philips Healthcare Ohio (See FSN 9234)
Xeleris 1.0, Xeleris 1.1, Xeleris 2.0, Xeleris 2.1 and Xeleris 3.0, GE Medical Systems Israel (See FSN 9261)
MHI - TM2000 (vero Linac system 1.0), Mitsubishi Heavy Industries (See FSN 9266)
Probes, pulse-co Oximeter, reusable/ Pronto-7 rainbow 4D Reusable Sensor ; Radical, Masimo (See FSN 9267)
Radiation therapy treatment record/verify system, Varian Medical Systems (USA) (See FSN 9273)
CADD R Solis Ambulatory Infusion Pump, SMITHS MEDICAL ASD, Inc (See FSN 9276)

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DG POST/matériovigilance

cardioPAT, Haemonetics Corp USA (See FSN 9278)
Brilliance 6, 10, 16, 16P, 40,64, ICT, ICT SP, Big Bore, Philips Healthcare Ohio (See FSN 9280)
TomoTherapy R Treatment Systems, TomoTherapy Incorporated (See FSN 9286)
Defibrillator/ Monitor, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD (See FSN 9287)
Desktop Pro TM , Elekta Ltd (See FSN 9299)
AXIOM Artis VB23A à VB23H, Siemens (See FSN 9300)
DERMABOND® Topical Skin Adhesive DERMABOND TM Mini Topical Skin Adhesive ETHICON Inc. (See FSN 9301)
VA34A_SP2/ Definition + flash, Siemens (See FSN 9302)
syngo Dynamics, Siemens (See FSN 9303)
MOBILETT XP, Siemens Medical Solution (See FSN 9304)
syngo RT Therapist, Siemens (See FSN 9305)
MOBILETT XP, Siemens Medical Solution (See FSN 9307)
Nimbus/ Nimbus Paediatric, Arjo Huntleigh (See FSN 9308)
Fluoroscopic x-ray system, image -intensified, PHILIPS BEST (See FSN 9309)
VARiS Vision, Varian Medical Systems (See FSN 9312)
Sigma Micro DIC, Varian Medical Systems (See FSN 9326)
VCARE R Vaginal-Cervical Ahluwalia's Retractor-Elevator, ConMed Corporation (See FSN 9332)
Triathlon PKR instruments, peg drill, Stryker Orthopaedics Mahwah (See FSN 9336)
VS III ventilators, ResMed Ltd (See FSN 9351)
ARIA, Varian Medical Systems (See FSN 9360)
Fraxel re:store R Dual Laser System, Solta Medical, Inc (See FSN 9369)
Lucas 2, Gambro Lundia AB (See FSN 9373)
PlivioPore/ PlivioPore, Osteoconductive Titan Structure, Synthes GmbH (See FSN 9385)
Level 1 Normothermic I.V. Fluid Administration Sets, SMITH MEDICAL ASD, Inc (See FSN 9387)
HeartAttendant, Micromed Cardiovascular, Inc. (See FSN 9391)
Alcon Custom Pak/ Microlance 30G x 1/2 Needles included in Select Modles of alcon Customs Paks, Alcon Laboratories (See FSN 9392)
NX - Image acquisition and processing station, AGFA GEVAERT NV (Medical division) (See FSN 9393)
Tige fémorale de reconstruction EXTREME, Amplitude (See FSN 9395)
Green Light IITM Laryngoscope Handle Green Light IITM Battery Cartridge, (See FSN 9406)
Reporting Tool, GE Medical Systems (FR) (See FSN 9408)
EndoVims; VSX10030HD/ 30° Coverable endoscopic camera - Camera endoscopique gainable 30°, VIMS (See FSN 9423)
Air Bubble Detector Module and Occluder Module, Terumo Cardiovascular Systems (See FSN 9425)
Monoaxial screws ODALYS, Kisco International (See FSN 9426)
Carescape B 850, GE Medical Systems Information Technologies (See FSN 9467)
IntelliVue Clinical Information Portfolio (ICIP), Philips Healthcare (See FSN 9507)
Secure Catch Pouch, Cory Bros Ltd (See FSN 9518)

Terumo Myocardial Protection Sets: Cardioplegia Table Line Connector, Terumo Medical Corporation (See FSN 9523)
Adapta, versa, EnPulse, Kappa 600, 700, 800, 900, Relia and Vitatron, Medtronic Inc. (See FSN 9541)
Kalix II Sterile, Newdeal SAS (See FSN 9546)
Philips, Philips and Neusoft Medical Systems Co., Ltd. (See FSN 9550)
GMD Universal Female Urinary Incontinence Sling, Generic Medical Devices, Inc. (See FSN 9557)
Brilliance 64, Brilliance Big Bore, Brilliance Ict, Brilliance Ict SP, Ingenuity CT, Philips Healthcare Ohio (See FSN 9559)
Brilliance 64, Brilliance Big Bore, Brilliance Ict, Brilliance Ict SP, Ingenuity CT, Philips Healthcare Ohio (See FSN 9560)
Therakos UVAR CTS Photopheresis System, Therakos (See FSN 9561)
Beamview, Siemens (See FSN 9565)
Syngo RT Therapist, Siemens (See FSN 9567)
AXIOM Artis Artis Zee Artis Zeego, Siemens (See FSN 9569)
Clinac, Varian Medical Systems (See FSN 9586)
TEMPOFILTER II, (See FSN 9595)
S8-3t Micro TEE Transducer, Philips Health Care (See FSN 9598)
Omniflush, B. BRAUN MEDICAL n.v. (See FSN 9603)
Ultraview SL, Spacelabs Medical (See FSN 9613)
Clinac, Varian Medical Systems (See FSN 9622)
X-ray remote controlled table, Stephanix (See FSN 9623)
Portable Bedside Capnograph/Pulse Oximeter, Tyco Healthcare (See FSN 9626)
Cortoss Delivery Gun, ORTHOVITA Inc. (See FSN 9647)
Avenir Mueller Stem, Zimmer (See FSN 9653)
2.24 programmer software version, Eros RONCAIA-SORIN BIOMEDICA CARDIO (See FSN 9662)
Carescape B850, Ge Healthcare Finland (See FSN 9663)
Paradym, Eros RONCAIA-SORIN BIOMEDICA CARDIO (See FSN 9664)
Carescape B650, Ge Healthcare Finland (See FSN 9665)
Optical Guidance Platform (OGP), Varian Medical Systems (USA) (See FSN 9669)
ARTISTE MV, 8139789, Siemens (See FSN 9673)
Optima MR450w, Discovery MR450, Discovery MR750, Signa HDx. Signa HDxt, Signa HFO, GE 1.5T Signa HDe, GE 1.5T Signa HDsv, Signa Excite 1.5T & 3T., Ge Medical Systems (See FSN 9682)
Infusable® Pressure Infusor InfusaScan™ Pressure Infusor, Vital Signs Devices (See FSN 9695)
Mammomat Inspiration, Siemens (See FSN 9711)
Syngo Imaging, Siemens (See FSN 9712)
ACUSON & SONOVISTA X300, Siemens Medical Solution (See FSN 9713)
Nikkiso blood tubing set for haemodialysis, Nikkiso Co. Ltd (See FSN 9718)
FLOW-i, Maquet (See FSN 9726)
7F SafeSheath Tearaway Kit – 13cm 9F SafeSheath Tearaway Kit – 13cm Transvalvular Insertion Tool Kit

SafeSheath® Sealing Adapter Kit SafeSheath® Sealing Adapter Kit with Wing Extension Kit, ORTHOVITA Inc. (See FSN 9728)
LogiCal® Pressure Monitoring System; TranStar® Pressure Monitoring System ; and NovaTrans® Pressure Monitoring System., Smiths Medical International, Ltd (See FSN 9753)
MS2 Mobile Stand (used with the MoorLD12 Laser Doppler Imager), Moor Instruments Ltd (See FSN 9787)
High/low Lifting bath electromechanic height adj., Meditechnik DE (See FSN 10866)
Gymna Couches, GYMNA UNIPHY (See FSN 11072)
Damon 3MX Bicuspid Brackets, Ormco Corporation (See FSN 11516)
Angled Surecan, B. Braun Medical Inc. (See FSN 11959)
Drill Bit Ø 2.5mm, L 220mm, 2-flute and Fixation Sleeve for Vectra System, Synthes GmbH (See FSN 11964)
IMPAX CV DICOMstore with Media Purge Daemon, Agfa HealthCare N.V. (See FSN 11985)
INTERLINK System BURETROL Solution Set with 150mL Burette (Ball-Valve Drip Chamber), Baxter Healthcare Corporation (See FSN 12052)
A.T.S. 3000 Tourniquet System, Zimmer, Inc. (See FSN 12057)
Tonometer Measuring Prisms, Haag-Streit AG (See FSN 12106)
CT-compatible Intubation Head Ring Assembly, Integra Burlington (See FSN 12236)
Seno Advantage 2.1 and Seno Advantage 2.2, GE Medical Systems (FR) (See FSN 12240)
(1)Visum Halogen Surgical Light, (2) Visum LED Surgical Light, (3) Stryker Flat Panel & Navigation Arm, Stryker Communications (See FSN 12245)
Swift Mobil, Etac Supply Center AB (See FSN 12438)
Quadra Trial Broach size 0 , code 01.10.10.045, Medacta International (See FSN 12505)
RUSCH Macintosh Laryngoscope Disp.Metallic Kit, M.A. ARAIN & BROTHERS (PVT) L TD. (See FSN 12555)
syngo Workflow MLR, Siemens AG (See FSN 12645)
Triathlon Baseplate Impactor Extractor, Stryker Orthopaedics Mahwah (See FSN 12883)
Philips IntelliVue Information Center iX, Philips Medical systems (Andover) (See FSN 12924)

6 Etudes cliniques / Klinische studie:

10 études cliniques ont été présentées / 10 studies werden gepresenteerd

PUBLIC

7 Varia :

- **Oxyconcentrateur**
- **les commissions de juillet et août 2013**

Suite à une décision collégiale, les commissions d'Evaluation de juillet et août sont annulées.

- **Simethicone**

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

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 :

06/06/2013 : Salle/Zaal 06D285

à 13h
om 13u