

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

COMPTE-RENDU DE LA REUNION DU 6 JUIN 2013
VERSLAG VAN DE VERGADERING VAN 6 JUNI 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		Emmanuelle Gay	P/A
Maries Merken	P/A	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	E/V
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

Vanackere Sebastien	Eglen Steve	Frédérique Meulders
Julie Roothoof	Sibylle Watteeuw	

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

nihil

4 Suivi des incidents/ Opvolging van de incidenten

- **stent XIENCE SBA EECSS (Side Branch Access Everolimus Eluting Coronary Stent System) du fabricant Abbott.**
- **Micromed Cardiovascular – HeartAssist 5 – dossier 12790**
- **Heartware – Heartware ventricular assist system – dossier 12321**
- **Boston Scientific – PT graphix GuideWire & PTCA dilatation catheter – dossiers 12099 & 12100**
- **Gambro – BL200BD Pre POST – dossier 11714**

5 Incidents

4 des 9 dossiers 'for discussion' ont été présenté oralement durant cette réunion dont :

- **BJR International – tige fémorale THA.hy.ti – dossier 12789**
- **Covidien – EGIA 60 Articulating Med / Thick Sulu – dossier 10806**
- **Kimberly-Clark Corp. – MIC* PEG PULL Feeding Tube, 14Fr – dossier 10110**
- **Unomedical – Quick Set Paradigm – dossier 11175**

106 FSCA sont soumis à la Commission / 106 FSCAs warden voorgelegd aan de Commissie

4DITC (4D Integrated Treatment Console), Varian Medical Systems (USA) (See FSN 7407)
BHR Acetabular Cup 52mm and 56mm (Models 74120152 and 74120156), Smith & Nephew Orthopaedics Ltd (See FSN 7413)
tergumed Extension: 30045, Proxomed Medizintechnik GmbH (See FSN 7431)
CryoAblation System, Medtronic CryoCath (See FSN 7546)
Endotracheal (ET) Tubes, Unomedical A/S (See FSN 7725)
AXIOM Artis, Siemens (See FSN 9306)
XVI, Elekta Ltd (See FSN 9443)
Arterial Line Kit 20G, Arterial Catheter Mini Kit 20GX6in, Arterial Line Kit 18G, One-Piece/Tuohy-BorstlIntroducer Tray 8F, Argon Medical Devices Inc. (See FSN 9570)
MitraClip Mitral Valve Repair System consisting of: Clip Delivery System and Steerable Guide Catheter, Abbott (See FSN 9648)
Passeo-18, Biotronik Ag (See FSN 9764)
Sireskop SX, AXIOM Sireskop SD and Luminos TF, Siemens (See FSN 9803)
DMLC, Elekta Ltd (See FSN 9812)
- IS Can CO2 Absorber., Dräger Medical systems (See FSN 9820)
SL Dual Capnography Module, Spacelabs Medical (See FSN 9824)
DICOM Q/R software version 1.1.4, Medtronic Navigation Inc. (See FSN 9825)
BD Venflon™ Pro Safety 18GA 1.3mm x 45mm, BECTON DICKINSON Infusion Therapy AB (See FSN 9828)
Clinac & TrueBeam, Varian Medical Systems (See FSN 9832)
Runthrough™ NS Tapered PTCA guide wire, Terumo Japan (See FSN 9856)
CRANIAL/ENT Navigation Software Unlimited 1.0 CRANIAL/ENT Navigation Software Essential 1.0 VectorVision Navigation Software Cranial/ENT 7.9 Kolibri Navigation Software Cranial/ENT 2.7, BrainLAB Sales GmbH (See FSN 9866)
Welch Allyn Viewsonic Display unit, Welch Allyn Ltd (See FSN 9868)
syngo RT Therapist, Siemens (See FSN 9880)
ARTISTE/ONCOR, Siemens (See FSN 9881)
AXIOM Luminos TF, Siemens (See FSN 9883)
Ysio (Ysio F and Ysio S), Siemens (See FSN 9918)
HUDSON RCI® HUMIDIFIER ADAPTOR for use with AQUAPAK®, Teleflex Medical (See FSN 9919)
syngo RT Therapist, Siemens (See FSN 9920)
Siemens Linear Accelerator, Siemens (See FSN 9921)
syngo Imaging, Siemens (See FSN 9923)
ACUSON X300, Siemens (See FSN 9924)
thermosept ER/thermosept ED, Schülke & Mayr GmbH (See FSN 9934)
ACUSON X300, Siemens (See FSN 9948)
da Vinci Si Surgical System, Intuitive Surgical (See FSN 9978)
Dash 3000, 4000, 5000, GE Medical Systems Information Technologies (See FSN 9985)
ACUSON SC2000 Mainframe, (See FSN 10028)
Diagnostic Medical Ultrasound Systems ACUSON S2000, Siemens Medical Solution (See FSN 10029)
ACUSON S2000 systems, (See FSN 10030)

PUBLIC

DG POST/matériovigilance

Gradient Cable Inspection - Aera, Skyra, (See FSN 10032)	
Gradient Cable Inspection - Symphony, Sonata, SATS, (See FSN 10033)	
Optima MR450w, Discovery MR450, Discovery MR750 (Premium products) Optima MR355 and Optima MR360 (Value products), Ge Medical Systems (See FSN 10121)	
Artiste MV ; 8139789, Siemens (See FSN 10128)	
Omnifuse Pumps and Omnifuse PCA Pumps, SMITH MEDICAL International Ltd. (See FSN 10156)	
MOSAIQ, Elekta CMS Software (See FSN 10227)	
COHERENCE Therapist, Siemens (See FSN 10248)	
syngo.plaza / syngo Imaging XS; System Label syngo.plaza 105 92 457 / syngo Imaging XS 104 96 279, Siemens (See FSN 10255)	
ARIA™, Varian Medical Systems (See FSN 10259)	
EIUS Tibial (Keeled) and Femoral Implants, Howmedica Osteonics Corporation (See FSN 10264)	
Clinac with OBI (On-Board Imager), Varian Medical Systems (See FSN 10279)	
BioloX OPTION Ceramic Femoral Head system see FSN, Zimmer (See FSN 10315)	
Amsco V-PRO 1 Low Temperature Sterilization System Amsco V-PRO 1 Plus Low Temperature sterilization System, Steris Corporation (See FSN 10328)	
GammaMed Flexible Probe with Blocking Washer, Varian Medical Systems (See FSN 10331)	
Accent DR and Anthem CRT-P Pacemakers, ST Jude Medical (See FSN 10361)	
Terumo Sarns™ Adult Rigid Intracardiac Sucker, Terumo Cardiovascular Systems (See FSN 10425)	
Eclipse Treatment Planning System, Varian Medical Systems (See FSN 10426)	
Femtosecond Laser Systems, AMO Manufacturing (See FSN 10450)	
da Vinci Surgical Systems User Manuals, Intuitive Surgical (See FSN 10462)	
EBW NM, Philips Healthcare Ohio (See FSN 10474)	
SharePlan 1.1, RaySearch Laboratories AB (See FSN 10498)	
Clinac®, Trilogy®, Trilogy Tx™ and Novalis Tx™, Varian Medical Systems (See FSN 10513)	
Bivona Tracheostomy Tubes, Smiths medical (See FSN 10531)	
MOSAIQ Oncology Information System, Siemens (See FSN 10551)	
MOSAIQ, Elekta CMS Software (See FSN 10558)	
Brainscan platform software, BrainLAB Sales GmbH (See FSN 10559)	
Guide wire, ELLA-CS (See FSN 10588)	
Argus 600, Codan Argus AG (See FSN 10590)	
High Definition 120 Multi-Leaf Collimator (HD120 MLC), Varian Medical Systems (See FSN 10599)	
SafeSheath? CSG? Coronary Sinus Guide Braided Core Hemostatic Introducer, SafeSheath? Worley Telescopic Braided Series Situs LDS 2 Lead Delivery System, ORTHOVITA Inc. (See FSN 10609)	
ACUSON & SONOLINE Antares, Siemens Medical Solution (See FSN 10616)	
Senographe Senographe Essential, GE Medical Systems (FR) (See FSN 10619)	DS
AXIS SPECT System IRIX SPECT System, Philips Healthcare Ohio (See FSN 10648)	
Serfas Energy probes Super 90-S, Stryker Endoscopy (See FSN 10651)	
Sulcoflex, Rayner Intraocular Lenses Limited (See FSN 10656)	
Knee tibial Tray and knee Tibial Bearing, Biomet UK Ltd (See FSN 10668)	
Art.25498 , Set deconnexion ?D? (R1952-3-103) (MDD Class IIa) Art.25499 , Set connexion ?C? (R1952-3-102) (MDD Class IIa) Art.38106 , set Désinfection (R1952-2-9) (MDD Class I), Laboratoires Lohmann & Rauscher (See FSN 10670)	

MitraClip Mitral Valve Repair System consisting of: Clip Delivery System and Steerable Guide Catheter, Abbott (See FSN 10675)
Axiom Luminus & Axiom Iconos, Siemens AG; Healthcare Sector; Business Unit AX (See FSN 10695)
syngo RT Oncologist syngo Suite for Oncology System, Siemens AG Healthcare, Geschäftsgebiet Radiation Oncology (See FSN 10696)
Syngo RT therapist, Siemens AG Healthcare, Geschäftsgebiet Radiation Oncology (See FSN 10697)
ONCOR& PRIMUS, SIEMENS nv. Medische Techniek (See FSN 10698)
Super torque MB Angiographic, Cordis Corporation (See FSN 10700)
Olympus ESG-400, Olympus Winter and Ibe (See FSN 10716)
Advantage Window server, Ge Medical Systems (See FSN 10731)
Senographe 2000D, GE Medical Systems (FR) (See FSN 10742)
Graseby MR10 Neonatal Respiration Monitor, SMITHS MEDICAL ASD, Inc (See FSN 10743)
Lifecare TM 5000 IV Pump Set, CeramOptec GmbH, a company of biolitec group (See FSN 11031)
FW099R, S4C OCCIPUT SCREW REMOVER FW101 R, S4C OCCIPUT SCREW REMOVAL SHAFT, Medtronic (See FSN 11033)
Surgical Light System iLED, Trumpf Medizin Systeme GmbH (See FSN 11446)
FLAMINGO Inflation device, PEROUSE MEDICAL (See FSN 11549)
Tess Shoulder Instrumentation compatible with Tess Glenoid Baseplate V2 T.E.S.S. Glenoid Reamer (S0/1) T.E.s.s. Glenoid Reamer (S2/3), Biomet (See FSN 11759)
Perimeter Octopus, Haag-Streit AG (See FSN 11785)
Beldico Haemodialyse Catheters / MF Cath, BELDICO SA (Belgian Diagnostic company) (See FSN 11945)
Affinity Four Birthing Bed, HILL-ROM (See FSN 11972)
PROXIMATE Skin Staple Extractor, Ethicon ENDO-SURGERY (See FSN 12213)
THA.hy.ti, BONE AND JOINT RESEARCH s.a. (BJR) (See FSN 12789)
Reusable Laryngoscope Handle, M.A. ARAIN & BROTHERS (PVT) L TD. (See FSN 12915)
Femoral Neck Screw Ø 11.0 mm, self-tapping, length 80 mm, Titanium Alloy (TAN), pink, Synthes GmbH (See FSN 12921)
Toffee Hammer, Biomet UK Ltd (See FSN 12942)
STERRAD 200 System Carriage, Advanced Sterilization Products (See FSN 12944)
STERRAD 100S Cassette, Advanced Sterilization Products (See FSN 12950)
HD Still Capture Image System, ConMed Linvatec (See FSN 12954)
VACUETTE Safety Blood Collection Set+XXX please refer to Annex 2 for details, Greiner Bio-One GmbH (See FSN 12964)
Edwards Crimper, Edwards Lifesciences (See FSN 12981)
X-tra fil Caps, Voco GmbH (See FSN 13023)
Medi-Trace Cadence RTS Defibrillation Electrodes, Covidien Healthcare (See FSN 13070)
Acuson SC2000, Siemens Medical Solution (See FSN 13082)
Tissue Liberator Blade UP, DePuy Mitek (See FSN 13083)
Burr Attachment, M, for EPD and APD Burr Attachment, L, for EPD and APD Synthes GmbH (See FSN 13195)

PUBLIC

6 Etudes cliniques / *Klinische studie:*

7 études cliniques ont été présentées / 7 studies werden gepresenteerd

7 Varia :

- **Augmentation mammaire avec l'acide hyaluronique**
- **Oxyconcentrateur**
- **La commission de juillet**

La Commission d'Evaluation est maintenue le 4 juillet 2013.

La réunion s'est clôturée à 14h10
De vergadering wordt voor gesloten verklaard om 14u10.

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 :

4/7/2013 : Salle/Zaal 06D285

à 13h
om 13u