

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

COMPTE-RENDU DE LA REUNION DU 5 SEPTEMBRE 2013  
VERSLAG VAN DE VERGADERING VAN 5 SEPTEMBER 2013

**Liste de présence – Aanwezigheidslijst**

<b>Membres Effectifs Effectieve leden</b>	P / A = Présent / Aanwezig E / V = Excusé / Verontschuldigd	<b>Membres suppléants Plaatsvervangende leden</b>	P / A = Présent / Aanwezig E / V = Excusé / Verontschuldigd
Els Tuyls	P/A	Marianne Van Malderen	E/V
Awatif Jebari	P/A	Emmanuelle Gay	P/A
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	Yves Taeymans	
Hein Heidebüchel		Rik Willems	
Kristel De Vogelare		Daniel Mojet	E/V
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	E/V
Bart Mersseman		Marine Debaut	E/V

**Représentants de l'AFMPS - Vertegenwoordigers van het FAGG**

Vanackere Sebastien	Damien Lambot	Dejehansart Aline
Vandenbroecke Cedric	Liesbeth Badisco	Sibylle Watteeuw
Eglen Steve		
Beuneu Claire	Beken Sonja	Pennickx Wim
Faelens Gerrit	Waucumont Catherine	Luchian Cristina

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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**

**5 Incidents**

19 dossiers 'for discussion' ont été présentés durant cette réunion :

- ***Riata and Riata ST silicone endocardial leads – dossier 10669***
- ***Micromed Cardiovascular, Inc.– dossier 11177***
- ***Alaris GP Large Volumetric Pump – dossier 12348***
- ***Omrix Pressure Regulator – dossier 12538***
- ***Folfusor SV2.5 ML/H – dossiers 12638, 12729, 12730, 12745, 12949, 13617, 13618, 13630 & 13745***
- ***HeartMate II Left Ventricular Assist Device - dossier 12796***
- ***Promus Element Everolimus Coronary Stent System 3.00x38mm - dossier 13011***
- ***Emerge - dossier 13016***
- ***MITRACLIP SYSTEM Clip Delivery System - dossier 13468***
- ***HeartStart MRx Defibrillator Monitor - dossier 13509***
- ***Gore Excluder AAA endoprosthesis - dossier 13702***

124 FSCA sont soumis à la Commission d'Evaluation / 124 FSCAs werden voorgelegd aan de Commissie

Internal defibrillation Handles and Internal Defibrillation Paddles, Physio-Control (See FSN 6768)
Bend A Beam ABC Handpiece, ConMed Corporation (See FSN 6942)
Loglysis - catheter for intravascular treatment 1725-2110, OptiMed Medizinische Instrumente GmbH (See FSN 7252)
Stratus OCT/optical Coherence Tomographer, Tyco Healthcare (See FSN 7268)
CyberKnife Robotic Radiosurgery System, Accuray Incorporated (See FSN 7271)
Hanaulux Blue 130, Hanaulux 2004/2005/3004/3005, ALM XTEN, Maquet S.A. (See FSN 7297)
Crossover TM Sheath Introducer, Thomas Medical (See FSN 7420)
Heartstart MRx; M3535A, M3536A, Philips Healthcare (See FSN 7536)
Skater Single Step and Choice Lock TCD, PBN Medicals (See FSN 7670)
cardioLife TEC-7621K and TEC-7631K cardioLife TEC-7721K and TEC-7731K, Nihon Kohden Corp. (See FSN 7732)
Axiom Artis, Siemens (See FSN 7793)
Breas iSleep 20, 20+, 20i, BREAS Medical AB (See FSN 7795)
3,2mm Guide Pin Sleeve 71674032, Smith & Nephew USA (See FSN 7940)
Cricket 3, Cypress 2, Ergolift, Ergolift 600, Ergostand, Explorer, Explorer 600, Graduate, Junior, Medilifter IV, Mezzo, Ministand, ML 4, Primo, Sherpa, SSL 2, Standup, Trekker, Xtreme, BHM Medical Inc. (See FSN 7956)
Argus A707, Argus A708 Infusion pump, Codan Argus AG (See FSN 7990)
Impella 2.5, Impella 5.0, Impella LD; 002137 (2.5), 004000 (LD), 004996 (5.0), Abiomed Europe GmbH (See FSN 8003)
Hamilton-C2 Model 160001/160002, Hamilton Medical AG (See FSN 8051)
Cecon 3000, Dialyse Wasseraufbereitungsanlagen GmbH & Co KG (See FSN 8119)
Coronary Artery Bypass Graft (CABG) Procedure Pak Products, Mölnlycke Health Care AB (See FSN 9404)
Transducer, Toshiba Medical Systems Corporation (See FSN 9435)
Filterine H Set INA/NEO Vitaline H Set INF/NEO, Oridion Medical 1987 Ltd. (See FSN 9580)
Biogel Eclipse Indicator System Biogel Eclipse Reveal System , Mölnlycke Health Care (See FSN 9643)
Connection Fixtures, Orto Maquet (See FSN 9758)
CYPHER SELECT®+ Sirolimus-eluting Coronary Stent, Cordis Europa N.V (See FSN 9797)
Carescape B850, Ge Healthcare Finland (See FSN 9809)
Lifepak R 500, Physio-Control (See FSN 9925)
Allura Xper FD10 (F/C), Allura Xper FD10/10 (avec table pour salle d'opérations), Allura Xper FD20, Allura Xper FD20/10, Allura Xper FD20/20 et AlluraCV20., PHILIPS BEST (See FSN 10122)
Eclipse Treatment Planning System, Varian Medical Systems (See FSN 10163)
Brilliance 64 and Ingenuity CT, Philips Healthcare Ohio (See FSN 10288)
PCR Eleva, Philips Medical Systems DMC GmbH (See FSN 10429)
Fluoroscopic X-ray System, PHILIPS BEST (See FSN 10607)
VitreaCore PET/CT feature of the Vitrea Enterprise Suite, Vital Images, Inc. (See FSN 10653)
Flow-i, Maquet (See FSN 10662)

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Riata and Riata ST silicone endocardial leads, Amgen (See FSN 10669)
Diagnost 94, Diagnost 96, Diagnost 97, PHILIPS BEST (See FSN 10681)
Duet TERS Universal straight and Articulating, single use, loading units, Covidien USA (See FSN 10851)
Eclipse Treatment Planning System, Varian Medical Systems (See FSN 11042)
Anaconda and Anaconda ONE-LOK Stent Graft Systems, Vascutek Limited (See FSN 11066)
HeartMate II Sealed Outflow Graft, HeartMate II Sealed Outflow Short Bend Relief, HeartMate II LVAS Implant Kit, THORATEC Corp (See FSN 11074)
Application Card software SynchroMed II Implantable Drug Pump, Medtronic Inc. (See FSN 11153)
12Fr SLS II Laser Sheath, The Spectranetics Corporation (See FSN 11169)
IMAGER™II Angiographic Catheter, Boston Scientific Corporation (See FSN 11192)
52-leaf Standard or Millennium MLC, Varian Medical Systems (See FSN 11195)
CE Intermate LV and CE Infusor LV, Baxter S.A. (See FSN 11313)
MEDRAD CONTINUUM PUM AND TUBING SET, MEDRAD, INC (See FSN 11385)
JET-X - PERI-LOC - IMHS-CP, Smith & Nephew USA (See FSN 11398)
TrueBeam, Varian Medical Systems (See FSN 11554)
DigitalDiagnost, Philips Medical Systems DMC GmbH (See FSN 11574)
.(Arjo / Arjohuntleigh) Minstrel (Medibo) Minerva (no longer in production) (Medibo) Gemini (no longer in production) (Medibo) Excelsior (no longer in production), ArjoHuntleigh AB (See FSN 11597)
Advantage Workstation Seno Advantage, GE Medical Systems SCS (See FSN 11623)
iPlan RT Dose 4.1, BrainLAB AG (See FSN 11644)
NO-Applikationsgerät; NO-A, EZ-KINOX, EKU elektronik GmbH (See FSN 11652)
ACUSON S2000, SIEMENS AG Medical Solutions, Ultrasound Division (See FSN 11690)
Artiste; Oncor; Primus, Siemens AG (See FSN 11692)
SCHILLER / Fred easy, Schiller Medical SAS (See FSN 11718)
SCHILLER, Schiller Medical SAS (See FSN 11719)
superDimension Bronchus System, superDimension, Inc (See FSN 11731)
VENTIlogic LS / VENTIlogic plus 15. Software version: <V2.05 - betroffen sind Geräte mit einem Firmware-Stand kleiner V2.05., Weinmann Geräte für Medizin GmbH (See FSN 11735)
EXCOR arterial cannula with graft CGRG-021, Berlin Heart (See FSN 11866)
IQ Geometrv Slit Knives Angled/Sharpoin, Surgical Specialties Puena Rico dba Angiotech (See FSN 11956)
ENLock et ENPlus, Abbott GmbH & Co. KG (See FSN 12025)
m3 Micro-Multileaf Collimator, BrainLAB AG (See FSN 12032)
VectorVision Cranial/ENT, BrainLAB AG (See FSN 12042)
Stockert SCP Perfusion System, Sorin Group Deutschland (See FSN 12044)
VITAL ? TEMP* GENERAL PURPOSE PROBE (Vital Signs Disposable General Purpose 9 French Temperature Probes), Vital Signs Colorado Inc. (See FSN 12096)
Sterile radiation protection gloves, KIRAN Medical Systems (See FSN 12102)
sat 805, sat 816, bitmos (See FSN 12163)
Temporary Cardiac Pacing Wire, Johnson & Johnson Medical n.v. - Belgique (See FSN 12175)
Alaris GP Large Volumetric Pump, CareFusion Switzerland (See FSN 12348)
SynchroMed II and SynchroMed EL Implantable Drug Pumps, Medtronic Inc. Minneapolis (See FSN 12349)

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Artis zeego, Siemens AG (See FSN 12382)
Brilliance CT Big Bore, EBW, GEMINI LXL, GEMINI TF 16, GEMINI TF 64, GEMINI TF Big Bore, Philips Healthcare Ohio (See FSN 12388)
DigitalDiagnost, Philips Medical Systems DMC GmbH (See FSN 12410)
Brilliance 64 and Ingenuity CT, Philips Healthcare Ohio (See FSN 12420)
Sarns™ Modular Perfusion System 8000, Terumo Cardiovascular Systems (See FSN 12443)
Terumo Advanced Perfusion System 1, Terumo Cardiovascular Systems (See FSN 12454)
Terumo? Advanced Perfusion System 1: Interface Modules for CDITM Systems & Serial Data Transfer, Terumo Cardiovascular Systems (See FSN 12455)
PACS-IW GE Centricity, GE Healthcare Integrated IT Solutions (See FSN 12473)
OEC 6800 MiniView C-arm, GE OEC Medical Systems, Inc (See FSN 12542)
MX 16-slice, MX4000, MX4000 Dual, MX 6000 Dual, Philips and Neusoft Medical Systems Co., Ltd. (See FSN 12554)
Aloka Prosound F75, Hitachi Aloka Medical Ltd. (See FSN 12613)
HomeChoice Automated PD System and HomeChoice PRO Automated PD System, Baxter S.A. (See FSN 12623)
Brilliance CT series (6, 10, 16, 16 Power, 40, 64, CT Big Bore and CT Big Bore Oncology), iCT, iCT SP, Ingenuity Core, Ingenuity CT and MX8000 Dual v. EXP, Philips Healthcare Ohio (See FSN 12627)
O-arm Imaging System, Medtronic Navigation Inc. (See FSN 12664)
AXIOM Iconos R200, Siemens AG Healthcare Sector - Imaging & IT Division - Magnet Resonance (See FSN 12706)
Pharos Vitesse, Biotronik Ag (See FSN 12718)
Deep Brain Stimulation (DBS) Lead Kits, Medtronic Inc. (See FSN 12734)
ADVANTX, INNOVA 2000, INNOVA 3100, INNOVA 4100, INNOVA 2100-IQ, INNOVA 3100-IQ, INNOVA 4100-IQ, GE Medical Systems (FR) (See FSN 12767)
MitraClip Mitral Valve Repair System consisting of: Clip Delivery System and Steerable Guide Catheter, Abbott vascular inc (See FSN 12801)
Terumo Syringe 50 ML luer lock, TERUMO EUROPE n.v. (See FSN 12804)
syngo.plaza, Siemens AG (See FSN 12822)
Flexiview 8800 Digital Mobil Imaging System, GE OEC Medical Systems, Inc (See FSN 12898)
Brilliance 64, Ingenuity CT, Ingenuity Core, and Ingenuity Core128, Philips Healthcare Ohio (See FSN 13045)
Occlusion catheter; hydraulic ureter dilatator, hydraulic urethral dilator, Willy Rüschi GmbH (See FSN 13202)
Diacap Ultra dialysis fluid filter., B. BRAUN AVITUM AG (See FSN 13281)
Temporary Cardiac Pacing Wire, Johnson & Johnson Medical n.v. - Belgique (See FSN 13305)
Transbond IDB Pre-Mix Chemical Cure Adhesive Kit, 3M Unitek Corporation (See FSN 13314)
da Vinci Surgical System, Intuitive Surgical (See FSN 13315)
QuickDraw Venous Cannula 22 Fr and 25 Fr, Edwards Lifesciences (See FSN 13324)
Alaris GP Large Volumetric Pump, CareFusion Switzerland (See FSN 13366)
Different packs and lots concerned- see attachment, Medline International France SAS (See FSN 13408)
VenaFlow Elite, DJO, LLC (See FSN 13415)
Dynamic Locking Screw Stardrive® Ø 5.0 and 3.7 mm, Synthes GmbH (See FSN 13431)
- IRIX 70 - IRIX 708 - NOVELIX 6510

- ORAMATIC558 , Carestream Health, Inc. (See FSN 13448)
All Infinia nuclear medicine systems, manufactured from 2003 - 2013: Infinia 3/8 Infinia-II 3/8 Infinia VC Infinia II VC Infinia 3/8 Hawkeye Infinia VC Hawkeye Infinia II 3/8 Hawkeye Infinia II VC Hawkeye Infinia II 3/8 HE4 Infinia II 5/8 HE4 Infinia II VC HE4 VG and VG Hawkeye nuclear medicine systems, manufactured from 1996 - 2003: Varicam Millennium VG 3/8 Millennium VG 5/8 Millennium VG 3/8 Hawkeye Millennium VG 5/8 Hawkeye Discovery VH Helix nuclear medicine systems, manufactured from 1992 ? 1996 (by Elscint Ltd). Devices added as part of this Follow Up Report: Brivo NM615 Discovery NM630 Optima NM/CT640 Discovery NM/CT670, GE Medical Systems Israel (See FSN 13466)
nanoFlex, STAAR SURGICAL (See FSN 13487)
Drill Bit Ø 5.0/7.3 mm, for SCFE Screw, Synthes GmbH (See FSN 13497)
Brilliance CT Systems and Gemini and Precedence Systems utilizing Brilliance CT, Philips Healthcare Ohio (See FSN 13498)
HeartStart MRx Defibrillator Monitor, Philips Medical systems (Andover) (See FSN 13509)
Celt ACD (6F) Femoral Artery Vascular Closure Device, Vasorum Limited (See FSN 13568)
MHI -TM2000 Linear Accelerator System/ VERO™ IINAC System/ MHI, Mitsubishi Heavy Industries (See FSN 13576)
GamCath Short-term catheter, Gambro (See FSN 13586)
WINGED SURECAN, B. Braun Medical Inc. (See FSN 13595)
RayStation, RaySearch Laboratories AB (See FSN 13613)
couvre-sonde sans latex avec gel pour trou de trepan / Bur Hole Latex Free Probe Cover With Gel, Microtek Medical (See FSN 13632)
Infusion-Perfusion-Transfusion sets and Aspiration sets, BELDICO SA (Belgian Diagnostic company) (See FSN 13634)
OmniPro Accept, IBA Dosimetry GmbH (See FSN 13657)
HydroSet Injectable HA Bone Substitute, Stryker Leibinger GmbH & Co (See FSN 13666)
PLATINUM, APELEM (See FSN 13717)
SWISS BI-MANUAL / MONO-MANUAL I/A SYSTEMS, Medical AG (See FSN 13738)
VISCOJECT 2.2 Inj. Set / VISCOJECT 1.8 Cart. Set, Medical AG (See FSN 13739)
Phaco Accessories Set, Medical AG (See FSN 13740)
MX 16-slice, MX4000, MX4000 Dual, MX 6000 Dual, Philips and Neusoft Medical Systems Co., Ltd. (See FSN 13741)

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Brilliance iCT and Brilliance iCT SP, Philips Healthcare Ohio (See FSN 13742)

**5 Etudes cliniques / Klinische studie:**

11 études cliniques ont été présentées / 11 studies werden gepresenteerd

**6 Varia :**

- **Augmentation mammaire avec l'acide hyaluronique**
- **Nouvelle méthodologie de travail**

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 :*

**3/10/2013 : Salle/Zaal 06D285**

à 13h  
*om 13u*