

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

**COMPTE-RENDU DE LA REUNION DU 07 MAI 2015  
VERSLAG VAN DE VERGADERING VAN 07 MEI 2015**

**Liste de présence – Aanwezigheidslijst**

<b>Membres Effectifs Effectieve leden</b>	<b>P / A = Présent / Aanwezig E / V = Excusé / Verontschuldigd</b>	<b>Membres suppléants Plaatsvervangende leden</b>	<b>P / A = Présent / Aanwezig E / V = Excusé / Verontschuldigd</b>
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 + Maboge Claude	E / V	Annie Vanderlinck	
Guido Van Nooten	P/A	Yves Taeymans	
Hein Heibüchel		Rik Willems	
Kristel De Vogelare		Daniel Mojet	P/A Président
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 Saevens	
Anne-Sophie Grell		Alex Rijnders	
Marc Cumps	E / V	Fien Aerts	
		Carole Absil	E / V
Bart Mersseman	E / V	Marine Debaut	P / A

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

Vanackere Sebastien	Watteeuw Sibylle	Debeuf Hélène
Lambot Damien	Jans Anne	Broekaert Annick
Badisco Liesbeth	Eglen Steve	Verhoye Ann
Roothoofst Julie	Demonceau Caroline	Van Der Linden Davy
Decaluwé Kelly		
Driesmans Christophe		

Le président ouvre la réunion à 13h00. Monsieur Van Nooten étant arrivé en retard, Monsieur Mojet à pris la présidence en main. Le quorum n'est pas atteint.

*De voorzitter opent de vergadering om 13u00. Het quorum werd niet bereikt.*

#### **1 Ordre du jour / Dagorde**

Goedgekeurd mits toevoeging van 4 variapunten:

- Terumo
- NuSurface studie

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

Approuvé / goedgekeurd

#### **3 Conflits d'intérêt / Belangenconflict**

Monsieur Maboge Claude (Fanc) a complété une Déclaration publique d'intérêts.

#### **4 Suivi des incidents / Opvolging van de incidenten**

2 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 2

Dossiers ont été présentés oralement durant cette Commission d'Evaluation

**Dossier 15236:** HeartStart XL (Philips Medical systems)

**Dossier 16506:** Contegra Pulmonary Valved conduit (Medtronic Inc.)

#### **5 Incidents**

geen dossier werd mondeling gepresenteerd tijdens deze Evaluatiecommissie / aucun dossier a été présenté oralement durant cette Commission d'Evaluation

## 70 FSCA sont soumis à la Commission / 70 FSCAs werden voorgelegd aan de Commissie

BD Obturators for Venflon, Insyte and Adsyte Pro, BECTON DICKINSON Infusion Therapy AB (See FSN 6002)
Optivantage DH injector System, Liebel Flarshheim Company (See FSN 6014)
Mölnlycke ProducePak, Mölnlycke Health Care AB (See FSN 6192)
Argyle Suction Catheter, Tyco Healthcare Ireland Ltd (See FSN 6224)
K-Flow Access catheters, Kimal plc (See FSN 6393)
Corpuls 3, GS Electromedizinische Geräte G. Stemple GmbH (See FSN 6617)
Alaris PK, Cardinal Health (See FSN 6687)
Arrow Central Venous Catheter (CVC) Systems, ARROW International (See FSN 6862)
CareVue Chart, Philips Healthcare (See FSN 6948)
Acuson S2000, Siemens Medical Solution (See FSN 7124)
Sarns Centrifugal Pump, Sarns Centrifugal Pump with X-Coating, Terumo Medical Corporation (See FSN 7265)
Monoplus violet 2/0 (3) 70cm 2xGR65 (M); Monoplus violet 3/0 (2) 70CM HS26S (M); MONOsyn Violet 0 (3.5) 70cm DS24 (M); monoplus violett 2/0 (3) 70cm HR2
Input TS and PS Introducer Sets With Needle, Medtronic Inc (See FSN 7880)
Lifepak R 15 defibrillator/monitor, Physio-Control (See FSN 7946)
Octopus Nuvo Tissue Stabilizer, Medtronic Inc. (See FSN 8689)
Eon MiniTM and BriotM Rechargeable Implantable Pulse Generators, St Jude Medical (See FSN 9790)
Eclipse Treatment Planning System, Varian Medical Systems (USA) (See FSN 12073)
Integrity, Elekta Ltd (See FSN 14484)
TENEO, Sirona Dental Systems GmbH (See FSN 14496)
XiO RTP System, IMPAC Medical Systems , Inc. (See FSN 14536)
ACUSON SC2000, Siemens Medical Solution (See FSN 14741)
XiO RTP System, IMPAC Medical Systems , Inc. (See FSN 14841)
TomoTherapy Hi-Art System, Accuray Incorporated (See FSN 15077)
Artis zeego, Siemens AG (See FSN 15229)
KRYO, Planer PLC (See FSN 15278)
EC--3890F12 Gas/Water Feeding Valve for Pentax video gastroscopes/colonoscopies, HOYA Corp., Pentax life Tokyo office (See FSN 15435)
IntelliVue MX40 Wearable Patient Monitor in use with the Philips IntelliVue Information Center IX (PIIC IX), Philips Medical systems (Andover) (See FSN 15668)
Hitachi Aloka, Hitachi Aloka Medical Ltd. (See FSN 15779)
C-Series High Energy Linear Accelerator, Varian Medical Systems (USA) (See FSN 15790)
Patient Data Manager, BrainLAB AG (See FSN 15804)
Software, Radiation Therapy Planning System, software versions 9.0, 9.2, 9.4 and 9.6., PHILIPS MEDICAL SYSTEMS (See FSN 16112)
Portico Transcatheter Aortic Heart Valve System, St Jude Medical (See FSN 16202)
EDS III, Codman & Shurtleff, Inc. (See FSN 16211)
Philips Expression IP5 Information Portal, Invivo Corporation (Philips Healthcare) (See FSN 16234)
Bone Level 4.1 mm RC SLActive 8 mm Roxolid, Institut Straumann AG (See FSN 16241)
EndoWrist® One Vessel Sealer, Intuitive Surgical (See FSN 16397)
PICO70, Radiometer Medical ApS (See FSN 16576)
green stream SY-P ARGUS 600, ARGUS 600, Codan Argus AG (See FSN 16584)
Stellaris PC Vision Enhancement System with Laser, Bausch & Lomb (See FSN 16611)
McGRATH® MAC2 Video Laryngoscope Blade, AIRCRAFT MEDICAL (See FSN 16653)
iPlan RT / iPlan RT Dose (all versions), BrainLAB AG (See FSN 16734)
Lentis Hydrosmart, Oculentis GmbH (See FSN 16735)
CURVED REINFORCED ENDOTRACHEAL TUBE - MURPHY EYE, HIGH VOLUME, LOW PRESSURE CUFF - STERILE PACKENDOSOFT ENDOTRACHEAL TUBE - LOW PRESSURE
Hitachi, Hitachi Medical Corporation (See FSN 16791)
Discovery IGS 730 and 740, GE Medical Systems SCS (See FSN 16853)
KFlow Epic Short Term Dual Lumen 6FR Catheters, Kimal plc (See FSN 16922)
FUJIFILM Digital Mammography System AMULET, FUJIFILM Corporation (See FSN 16926)
HYDRORISE LIGHT FAST, Zhermack (See FSN 16937)
Philips IntelliVue Information Center IX, Philips Medical systems (Andover) (See FSN 16954)
Brainlab Offset Cup Impactor Universal, BrainLAB AG (See FSN 16968)
AIRO Mobile CT System, Mobius Imaging, LLC (See FSN 16984)
Dressing Electrode 15x15cm (10x10cm), Mölnlycke Health Care AB (See FSN 16994)
Single Limb Circuit for PneuPac® Ventilators, with PEEP Valve, Smiths Medical International LDT (See FSN 17002)
ISKD Intramedullary Skeletal Kinetic Distractor, Orthofix (See FSN 17003)
Ivory Reamer®, 10mm /6 Teeth, Stryker Trauma AG (See FSN 17009)
CADD™ Medication Cassette Reservoir, SMITHS MEDICAL ASD, Inc (See FSN 17084)
FlowSENS, MEDEX S.A. (See FSN 17131)
Medumat Transport with and without CO2-measurement, Weinmann Geräte für Medizin GmbH (See FSN 17202)
CryoFlex 10cm Surgical Ablation ProbeCryoFlex 10-S Surgical Ablation ProbeCryoFlex 7cm Surgical Ablation ProbeCryoFlex 10cm Surgical Ablation Probe with Clamp, LP Rotare, Ossur (See FSN 17283)
MEDUMAT-Beatmungsgeräte mit blauemPrüfbeutel, Weinmann Geräte für Medizin GmbH (See FSN 17326)
Acumed 1.5 mm and 2.3 mm MultiScrew Depth Gauges, Acumed LLC (See FSN 17344)
Retrograde Cardioplegia Cannula, ANDOCOR n.v. (See FSN 17394)
Artis Q, Artis Q.zen, Siemens AG (See FSN 17408)
Conquest PTA Balloon Dilatation Catheter, Bard Peripheral Vascular (BPV) (See FSN 17411)
Aspen/Alpine and Lineum Torque Handles, Biomet Spine LLC (See FSN 17471)
GE MR Systems - refer to comments for product list, GE Medical Systems Information Technologies (See FSN 17480)
TIGERPAW System II, LAAx, Inc (See FSN 17484)
FORTE AXIS Gemini 16 PET/CT System Forte-JetStream - AZ Precedence 16 Precedence 6 SliceIngenuity PET/MR Gemini GXL 16 SliceGEMINI LXL TruFlight Select PE
DAP DIPHOTERINE, Prevor Eyewash (See FSN 17537)

## 6 Etudes cliniques / Klinische studies

7 études ont été présentées / 7 studies werden gepresenteerd

**PUBLIC**

**7 Varia**

- 1- NuSurface kunstmeniscus studie (firma Active Implants)
- 2- Terumo
- 3- Stent Terumo

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 :*

**02/04/2015 : Salle/Zaal Vivaldi**

à 13h00  
*om 13u00*