

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

**COMPTE-RENDU DE LA REUNION DU 05 MAART 2015
VERSLAG VAN DE VERGADERING VAN 05 MAART 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	P / A
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 Président	Yves Taeymans	
Hein Heibüchel		Rik Willems	
Kristel De Vogelare		Daniel Mojet	P / A
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	E / V	Fien Aerts	
		Carole Absil	E / V
Bart Mersseman	P / A	Marine Debaut	P / A

Représentants de l'AFMPS - Vertegenwoordigers van het FAGG

Vanackere Sebastien	Vandenbroucke Cédric	Van de Vijver Pieter
Lamot Damien	Dejehansart Aline	Jans Anne
Badisco Liesbeth	Eglen Steve	Delaere André
Roothoofst Julie		Debeuf Hélène
		Cristina Luchian

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

Goedgekeurd mits de variapunten die voor de klinische studies besproken zullen worden wegens teleconferentie om 14u00.

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

Approuvé / goedgekeurd

3 Conflits d'intérêt / Belangenconflict

Nihil / nihil

4 Suivi des incidents / Opvolging van de incidenten

0 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie /

0 dossiers ont été présentés oralement durant cette Commission d'Evaluation

5 Incidents

1 dossier werd mondeling gepresenteerd tijdens deze Evaluatiecommissie / 1 dossier a été

présenté oralement durant cette Commission d'Evaluation

Dossier 15477: Multilayer Flow Modulator (Cardiatis)

67 FSCA sont soumis à la Commission / 67 FSCAs werden voorgelegd aan de Commissie

Acuson Sequoia 512, (See FSN 5525)
HomeChoice and HomeChoice PRO, Baxter Healthcare Corporation (See FSN 2053)
MEDEX, MEDEX S.A. (See FSN 2471)
MAGNETOM Systems Sonata syngo MR, Siemens (See FSN 3079)
MAGNETOM Systems (Harmony / Symphony / Sonata / Allegra / Trio / Novus), Siemens (See FSN 3849)
Conveen Urine Bags- standard 1500 ml- sterile/non-sterile, Coloplast A/S (See FSN 4542)
INFINIA, GE Medical Systems Israel (See FSN 6273)
Precision RXI, Precision RXI-e, General Medical Merate S.P.A (See FSN 6115)
ExacTrac Infrared Tracking Platform 5.0, 5.5, BrainLAB Sales GmbH (See FSN 6242)
C-Series Clinacs, Acuity and Ximatron / Exact, Varian Medical Systems (See FSN 6239)
Centricity RA 1000, Healthcare Integrated IT Solutions (See FSN 6061)
ARTISTE - SAL Accessory Holder, Siemens (See FSN 6684)
Desktop Pro Control System, Elekta Ltd (See FSN 6694)
AXIOM Luminos dRF ; 10094200, Siemens (See FSN 6522)
XVI, Elekta Ltd (See FSN 6842)
ARIA, Varian Medical Systems (See FSN 6841)
BrightView Gamma Camera, PHILIPS MEDICAL SYSTEMS (See FSN 7140)
MEVATRON /PRIMUS Mid ; PRIMART MX ; ONCOR ; MEVATRON, Siemens (See FSN 7154)
Hi-Art System, TomoTherapy Incorporated (See FSN 7193)
Oncentra Brachy, NUCLETRON B.V. (See FSN 7962)
Zimmer Low Density Polyethylene (LDPE) Bag Notification, Zimmer, Inc. (See FSN 13866)
Philips HDI 4000, Philips Nederland B.V. (See FSN 3690)
Centricity RA 1000, Healthcare Integrated IT Solutions (See FSN 6060)
Cinac 21EXS, Cinac 2100C and Cinac 2300, Varian Medical Systems (See FSN 6855)
MAGNETOM Systems (Harmony / Symphony / Vision / Sonata / Avanto / Espree), Siemens (See FSN 3892)
Precise treatment table, Elekta Ltd (See FSN 6690)
SAM Junctional Tourniquet, SAM Medical Products (See FSN 16553)
SYNCHROMED II and Synchromed EL implantable drug pumps, Medtronic Inc. (See FSN 13364)
SYNCHROMED II and Synchromed EL implantable drug pumps, Medtronic Inc. (See FSN 13363)
Zeus IE, Dräger Medical (See FSN 15552)
Plum XL familyLifeCare 5000, Hospira Inc. (See FSN 14467)
Receptal System Liners and Canisters, Hospira (See FSN 13981)
Teleflex ISISTM Tracheal Tube with Subglottic Secretion Suction Port, Teleflex Medical (See FSN 14819)
BrightView SPECTBrightView X BrightView XCT, Philips Healthcare Ohio (See FSN 14628)
MiniCap Extended Life PD Transfer Set with Twist Clamp, Baxter Healthcare Corporation (See FSN 15465)
SYNCHROMED II and Synchromed EL implantable drug pumps, Medtronic Inc. (See FSN 13362)
Breathing Circuits, Vital Signs Colorado Inc. (See FSN 15111)
FOLFusor SV 0.5ml/h system, Baxter Healthcare Corporation (See FSN 15349)
Accu-Chek Spirit Combo, ROCHE DIAGNOSTICS GMBH (See FSN 16270)
Ingenia, Philips Medical Systems BV (See FSN 15797)
NOVACELL NV - LC 02 AND VANSON V - 95, Vision Sciences (See FSN 16137)
KFlow Epic Catheter Range, Kimal plc (See FSN 16395)
ATTUNE® INTUITION™ IMPACTION HANDLE AND IMPACTORS, DePuy Orthopaedics Worldwide Ltd (See FSN 16717)
cryoLCE cryo-ablation probe, AtriCure Inc. (See FSN 16637)
Ysio, Siemens AG Healthcare Sector - Imaging & IT Division - Magnet Resonance (See FSN 16197)
NexGen Complete Solution MIS Total Knee Procedure, Zimmer GmbH (See FSN 15715)
Ysio Max; Luminos dRF Max; Luminos Agile Max; Uroskop Omnia Max, Siemens AG Healthcare Sector - Imaging & IT Division - Magnet Resonance (See FSN 16214)
BrightView XCT Imaging System, Philips Healthcare Ohio (See FSN 15827)
GEMINI TF 16 PET/CTGEMINI TF 64 PET/CT GEMINI TF Big Bore, Philips Healthcare Ohio (See FSN 15788)
All VG and VG Hawkeye nuclear medicine systems, manufactured from 1996 - 2003:• Millennium VG• Millennium VG and Hawkeye• Discovery VH• VaricamAll Infinia Hercules 360 Universal Stabilizing Arm, top mount, Terumo Cardiovascular Systems (See FSN 16456)
ZOLL Pro-padz Sterile Multi-Function Electrodes, ZOLL Medical Corporation (See FSN 16638)
IntelliVue Clinical Information Portfolio (ICIP), Rev DIntelliVue Clinical Information Portfolio (ICIP), Rev EIntelliSpace Critical Care & Anesthesia (ICCA), Rev FIntelliS V-max Schiebehilfe, AAT Alber Antriebstechnik GmbH (See FSN 16715)
Camino® Intracranial Pressure Monitoring Kits, Integra Neuro Sciences (See FSN 15825)
Toptex lite (single product) and in set systems, Lohmann & Rauscher Rengsdorf (See FSN 16688)
AMS 700 Accessory Kit, American Medical Systems (See FSN 16598)
INFINITI® Ultrasound Pak, Alcon Laboratories Inc. (See FSN 16517)
CODAN ARGUS 606 S, CODAN ARGUS 717 V, Codan Argus AG (See FSN 16236)
OMNIFIX 20ML LUER SOLO, B. Braun Melsungen AG (See FSN 16438)
Trident PSL HA Solid Back 50MM, Stryker Orthopaedics (See FSN 16806)
all Artisan and Artiflex IOLs, Ophtec bv (See FSN 16973)
STERRAD Cassettes, Advanced Sterilization Products (See FSN 16661)
da Vinci Si™ Surgical System, Intuitive Surgical (See FSN 16792)
ATTUNE Intuition Distal Femoral Jig, DePuy Orthopaedics Worldwide Ltd (See FSN 16513)
MTERPACK ENDOREC, Aspide Medical (See FSN 16803)
AquaPak SW/EAU Sterile, 340ml w/Adaptor040 Humidifier Adaptor, ShelfpakAquaPak 340 Sterile Water, 340ml w/040 Adaptor, FrenchAquaPak 340 Sterile Water, 34

6 Etudes cliniques / Klinische studies

7 études ont été présentées / 7 studies werden gepresenteerd

PUBLIC

7 Varia

- 1- MOM
- 2- Réclassification

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 :

02/04/2015 : Salle/Zaal Vivaldi

à 13h00
om 13u00