

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

COMPTE-RENDU DE LA REUNION DU 02 FEVRIER 2017
 VERSLAG VAN DE VERGADERING VAN 02 FEBRUARI 2017

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	E / V	Emmanuelle Gay	E / V
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	E / V
Wim Verlinden		Thierry Descamps	
Dominique Wouters		Tinne Leysen	
Christine Barzin		Jan Saevels	
Anne-Sophie Grell		Alex Rijnders	
Marc Cumps	E / V	Fien Aerts	
		Carole Absil	E / V
Bart Mersseman		Marine Debaut	

Représentants de l'AFMPS - Vertegenwoordigers van het FAGG

Damien Lambot	Cedric Vandenbroucke	Aline Dejeansart	
Sibylle Watteuw	Gregory Duby	Pieter van de Vijver	Ann Jans
Kelly Decaluwé	Julie Roothoof	Alexandre Jauniaux	
Melidis Christos (FANC)			

Le président ouvre la réunion à 13h. Le quorum n'est pas atteint.

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

1 Ordre du jour / Dagorde

Approuvé / goedgekeurd

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

Approuvé / goedgekeurd

3 Conflits d'intérêt / Belangenconflict

Non / Nee

4 Incidents / Incidenten

4 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 4 dossiers ont été présentés oralement durant cette Commission d'Evaluation

- ✓ Dossier 20881 (DAT) : HeartMate II® Left Ventricular Assist Device
- ✓ Dossier 21097 (CCV) : SYNERGY™
- ✓ Dossier 21174 (DLT) : Nuvia SI Anterior
- ✓ Dossier 21183 (DLT) : Convey Guiding Catheter Guiding Catheter

5 Suivi des incidents / Opvolging van de incidenten

69 FSCA werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 69 FSCA ont été présentés oralement durant cette Commission d'Evaluation:

LIKO SlingBar 350, SlingBar 360, SlingBar Wide 670 and SideBar Standard, Liko (See FSN 14060)

Samaritan PAD, HeartSine Technologies Ltd. (See FSN 14901)

GLUMA Desensitizer PowerGel 4x1 g & Sample Kit 1x1g, Heraeus Kulzer GmbH (See FSN 15353)

Brilliance CT 6, Brilliance CT 10, Brilliance CT 16, Brilliance CT 16 Power, Brilliance CT 40, Brilliance CT 64, Brilliance CT Big Bore Radiology, Brilliance CT Big Bore Oncology, Brilliance iCT, Brilliance iCT SP, Ingenuity CT, Ingenuity Core, Ingenuity Core128, MX8000 Dual v. EXP, Ingenuity Flex, Philips Healthcare Ohio (See FSN 15386)
Symbia T camera /Symbia Intevo camera systems, Siemens Medical Solutions USA, Inc. (See FSN 16051)
Triathlon Femoral scorpio femoral restoration WE, Stryker Orthopaedics Mahwah (See FSN 16099)
Orthopaedic Prosthesis Implantation Instrument, Stryker Orthopaedics Mahwah (See FSN 16328)
Lithium Polymer Fiber Optic Module Batteries used in the Intera MR System upgraded to CDAS, Philips Medical Systems BV (See FSN 16732)
HeartStart MRx Defibrillator/Monitor, Philips Medical systems (Andover) (See FSN 16744)
Colleague 3 Pump v.17, Baxter Healthcare SA (See FSN 16776)
DePuy Synthes Trauma RIA System / RIA Tube Assembly, for RIA Drive Shaft minimum length 360 mm, Synthes GmbH (See FSN 16789)
PowerLED& HLED, STANDOP VOLISTA, XTEN, HLX3000, Maquet S.A. (See FSN 16826)
MPT7-4 Multi-plane Transesophageal Transducer, Philips Ultrasound (See FSN 16863)
Syringe tip cap, Baxa Corporation / Baxter Healthcare Corporation (See FSN 16991)
DHS Connecting Screws, Synthes GmbH (See FSN 17556)
Eon Wall charger and Eon Portable Charger, Advanced Neuromodulation Systems (See FSN 17653)
AGFA Digital Radiography X-Ray system DX-D 100, AGFA GEVAERT NV (Medical division) (See FSN 17895)
BEAVER 4.0mm Banana Blade, Smith & Nephew Andover (See FSN 19316)
Vygon nutrisafe C-GON Enteral syringes 20ml, Laboratoires pharmaceutique Vygon SA (See FSN 19377)
CyberKnife Robotic Radiosurgery System, Accuray Incorporated (See FSN 19425)
Physio-Control QUIK-COMBO® pacing/defibrillation/ECG electrodes with EDGE System™ technology and REDI-PAK® preconnect system, Physio-Control (See FSN 19492)
Vaxcel™ PICC, Xcela™ PICC & BioFlo™ PICC, Navilyst (See FSN 19813)
Fetch™ 2 Aspiration Catheter, Boston Scientific Corporation M (See FSN 19845)
Perceval Sutureless Aortic Heart Valve, Sorin Group Italia Srl (See FSN 20847)
XARIO 100, XARIO 200, Toshiba Medical Systems Corporation (See FSN 20866)

SIGNA Creator/ SIGNA Explorer, GE HEALTHCARE (TIANJIN) COMPANY LIMITED (See FSN 20898)
5.2mm Suction Punch, Smith & Nephew USA (See FSN 20994)
Operating table top U 14/ U24 H/ U26 H, Trumpf Medizin Systeme GmbH (See FSN 21015)
Devon Light Glove, Covidien Healthcare (See FSN 21076)
LECTROGUARD, Laboratoires pharmaceutique Vygon SA (See FSN 21078)
Fujifilm Synapse PACS, FUJIFILM Medical System USA, Inc. (See FSN 21082)
Brivo OEC 715/785/865, GE Hualun Medical Systems Co Ltd (See FSN 21112)
Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™, ST Jude Medical CRMD (See FSN 21119)
Barrier® Hip Set, Molnlycke Health Care AB (See FSN 21164)
Java Posterior stabilization System,, Zimmer Spine (See FSN 21173)
Charging System, RestoreSensor Charging System, Medtronic Inc. Minneapolis (See FSN 21179)
Nellix EndoVascular Aneurysm Sealing System, Endologix International Holdings B.V. (See FSN 21187)
SFS-5-25P Balloon Infusers, Nipro Corporation (See FSN 21213)
Innova x100, GE Medical Systems SCS (See FSN 21230)
Custom kits with Clarify Visualization System / Clarify Visualization System (Item code: 21-345), Covidien Healthcare (See FSN 21234)
Defibrillation electrode SCHILLER DF87C and DF56C, Leonhard lang Medizintechnik GmbH (See FSN 21243)
MEDRAD Intego™ PET Source Administration Sets, Bayer Medical Care Inc. (See FSN 21335)
RayStation, RaySearch Laboratories AB (See FSN 21339)
KASIOS SAS (See FSN 21357)
modular neck hip prostheses - Modular SMF™ et Modular REDAPT, Smith & Nephew USA (See FSN 21383)
AXIOM Artis systems with SW version VB35E, Siemens AG (See FSN 21390)
OPTIPAC BONE CEMENT, BIOMET orthopaedics (See FSN 21399)
Terrafor ventre plat, Terrafor Ventre Plat Duo, Laboratoire Claytone (See FSN 21420)
Platinum dRF, APELEM (See FSN 21444)
Forefoot 1.5 set, Newdeal SAS (See FSN 21448)
FUJIFILM Flexible Duodenoscope, FUJIFILM Corporation (See FSN 21449)

Total metatarsophalangeal joint prosthesis, Wright Medical Technology, Inc. (See FSN 21450)
CONTOUR DIABETES App, Ascensia Diabetes Care Holdings AG (See FSN 21479)
Merge Eye Station, Merge Healthcare (See FSN 21512)
Claria MRI™ CRT-D SureScan™ and Amplia MRI™ CRT-D SureScan™, Medtronic Inc. Minneapolis (See FSN 21527)
iPlan RT Dose / iPlan RT, BrainLAB AG (See FSN 21539)
Artis Q / Artis Q zen systems and SW version VD11B, Siemens AG (See FSN 21544)
Impactor for PFNA Blade, Synthes GmbH (See FSN 21578)
Screwdriver handle, T-shape, cannulated, AO-style, Zimmer GmbH (See FSN 21586)
Autoflush, Laboratoires pharmaceutique Vygon SA (See FSN 21606)
AFX EndoVascular AAA System, Endologix International Holdings B.V. (See FSN 21609)
Nellcor Forehead SpO2 Sensor, Covidien Healthcare (See FSN 21619)
SynchroMed® II Programmable Pump, N'Vision Application Card, Medtronic Inc. (See FSN 21625)
Flexible video rhinolaryngoscope, HOYA Corporation Medical Instrument Division (See FSN 21639)
Sonata Radiofrequency Ablation Handpiece, Gynesonics Inc. (See FSN 21650)
LazerEdge Knives, Bausch & Lomb - Optics center (See FSN 21664)
URF-V2 / URF-V2R flex. videoureteroscope, Olympus medical Systems Corporation (See FSN 21678)
URF-P6 URETERO-RENOFIBERSCOPE, Olympus medical Systems Corporation (See FSN 21679)
DuraDiagnost (Model#712210, 712211), DuraDiagnost Compact (Model#712212, 712213), Philips Healthcare (Suzhou) Co.,Ltd (See FSN 21705)

6 Etudes cliniques / Klinische studies

7 études cliniques ont été présentées à la Commission / 7 Klinische studies werden gepresenteerd tijdens de Evaluatie Commissie

7 Varia

- ✓ Mitra Clip (CCV)
- ✓ G4 PLATINUM and G5 Mobile receiver (KYD)
- ✓ Modulateur de flux (Alexandre Jauniaux)

La réunion s'est clôturée à 14h00
De vergadering wordt voor gesloten verklaard om 14h00

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 :

09/03/2017 : Salle/Zaal Vivaldi

à 13h00
om 13u00