

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

COMPTE-RENDU DE LA REUNION DU 09 MARS 2017
VERSLAG VAN DE VERGADERING VAN 09 MAART 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		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	
Bart Mersseman		Carole Absil	E / V
		Marine Debaut	

Représentants de l'AFMPS - Vertegenwoordigers van het FAGG

Damien Lambot	Cedric Vandenbroucke	Ann Jans
Sibylle Watteuw	Gregory Duby	Christophe Driesmans
Kelly Decaluwé	Julie Roothoof	

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

Een kleine tyfout werd aangepast in het verslag van de vorige commissie.

3 Conflits d'intérêt / Belangenconflict

Non / Nee

4 Incidents / Incidenten

2 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 2 dossiers ont été présentés oralement durant cette Commission d'Evaluation

- ✓ Dossier 20152 (KYD) : Genius - Fresenius
- ✓ Dossier 19596 (KYD) : G4 Platinum and G5 Mobile receiver - Dexcom

5 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 21431 (GDY) : HeartWare Ventricular Assist System (Heartware Inc)
- ✓ Dossier 21758 (DLT) : SQUID (Embo-Flüssigkeiten)

En 104 FSCA / et, 104 FSCA:

ADM MDM Ball Impactor Tip and ADM Rim Impactor Tip, Stryker Ireland (See FSN 14046)
HeartStart MRx Defibrillator/Monitor, Philips Medical systems (Andover) (See FSN 14946)
HeartStart MRx Defibrillator/Monitor, Philips Medical systems (Andover) (See FSN 14950)
Povidone-Iodine MiniCap, MiniCap with Povidone-Iodine, MiniCap with Povidone-Iodine, Baxter Healthcare SA (See FSN 17056)
EVOLUTION / EVIDENCE, Stephanix (See FSN 17117)
TRILUX Operating Lighting System AURINIO L 120 PM std. Kard Motor Kamv HD A and related Monitor holder, Trilux Medical GmbH & Co. KG (See FSN 17120)
PHYSIONEAL, Baxter Healthcare SA (See FSN 17138)
TRILUX Examination Light Aurinio L 50, Trilux Medical GmbH & Co. KG (See FSN 17143)
Thoracic Vent Procedure Tray, Uresil LLC (See FSN 17238)
Getinge 86-series, Getinge Disinfection AB (See FSN 17744)
OxiMax N-65 & N-560 Pulse Oximeter, Covidien Healthcare (See FSN 17755)
HeartWare Ventricular Assist System, HeartWare Inc (See FSN 17772)
Oncor, Primus, Siemens AG (See FSN 17801)
Unomedical (See FSN 17815)
MAGNUS Hybrid OR table column, Orto Maquet (See FSN 17820)
astraira software for women's health, astraira software gmbh (See FSN 17834)
LifeCycle for Prenatal Screening, Wallac Oy (See FSN 17837)
VENTILATEUR PULMONAIRE MONNAL T60, AIR LIQUIDE MEDICAL SYSTEMS (See FSN 17846)
SofPort Advanced Optics Aspheric IOI. SoFlex SE Fo, Bausch & Lomb (See FSN 17880)
NOxBOX, Bedfont Scientific Limited (See FSN 17910)
Cook LapSac Surgical Tissue Pouch, Cook Incorporated (See FSN 17934)
HeartPAP, Philips Respironics (See FSN 17949)
prismaCR, SOMNOventCR, Weinmann Geräte für Medizin GmbH (See FSN 17950)
Vygon nutrisafe C-GON Enteral syringes, Laboratoires pharmaceutique Vygon SA (See FSN 18076)
iPlan RT Dose, BrainLAB AG (See FSN 18094)
ExacTrac v. 6.0.0 - 6.0.5, BrainLAB AG (See FSN 18293)
microflex, Laboratoires pharmaceutique Vygon SA (See FSN 18306)
TRIGEN 8/7mm x 24cm Humeral Nail, Smith & Nephew USA (See FSN 18311)

Plum Infusion Pump, Hospira (See FSN 18312)
Vygon nutrisafe C-GON Enteral syringes 20ml, Laboratoires pharmaceutique Vygon SA (See FSN 18315)
Actifuse ABX, Actifuse MIS System, Inductigraft, Apatech Limited (See FSN 18401)
MEDUMAT Transport, WEINMANN Emergency Medical Technology GmbH + Co. KG (See FSN 18413)
Syngo, Siemens AG (See FSN 18420)
GE Healthcare 3.0T MRsystems:refer to comments box, GE Medical Systems Information Technologies (See FSN 18491)
LFIT V40 Tapers, V40 Tapers and PCA Tapers, Stryker Orthopaedics (See FSN 18504)
HeartMate II LVAS System Controller, THORATEC Corp (See FSN 18513)
PORT-A-CATH® Plastic Hub Bent Needle, SMITHS MEDICAL ASD, Inc (See FSN 18524)
HF440, Infomed S.A (See FSN 18525)
SOLUSCOPE SERIE 4 PA SOLUSCOPE endoscope washer-disinfector, SOLUSCOPE SAS (See FSN 18620)
Accessory for haemodialysis, Gambro Dasco (baxter) (See FSN 18631)
CENTRICITY PACS IW WITH UNIVERSAL VIEWER, GE Healthcare Integrated IT Solutions (See FSN 18638)
MODULARIS Variostar, Siemens AG Healthcare Sector - Imaging & IT Division - Magnet Resonance (See FSN 18648)
BVI CustomEyes® Ophthalmic Procedure Kits, Beaver Visitec International Limited (See FSN 18693)
NxStage System One, NxStage Medical, Inc. (See FSN 18789)
LeMaitre Single Lumen Embolectomy Catheter, LeMaitre Vascular, GmbH (See FSN 18804)
Over-the-Wire Embolectomy Catheters, LeMaitre Vascular, GmbH (See FSN 18805)
Extension Device, Maquet (Rastatt) (See FSN 19539)
FOX, INVACARE Deutschland (See FSN 20034)
Edwards Commander Delivery System, Edwards Lifesciences (See FSN 20179)
Heating unit, pad, water, system - Heater/Cooler 1T, Heater/Cooler 3T, FlexTherm, Sorin Group Deutschland (See FSN 20379)
Merge PACS, Merge Healthcare (See FSN 20431)
iConnect Enterprise Archive, Merge Healthcare (See FSN 20432)
iConnect Enterprise Archive, Merge Healthcare (See FSN 20433)
OrthoCase, Merge Healthcare (See FSN 20434)

Eye Station, Merge Healthcare (See FSN 20435)
iConnect Enterprise Archive, Merge Healthcare (See FSN 20438)
Scorpio Patella Assembly Instrument, Stryker Orthopaedics Mahwah (See FSN 20740)
ED-FLOW AER, ED-FLOW SD AER, Getinge Lancer SA (See FSN 20902)
Accessory Adapter, Maquet (Rastatt) (See FSN 20935)
RayStation, RaySearch Laboratories AB (See FSN 20945)
TCM5, Radiometer Medical ApS (See FSN 20990)
Twin-Pass, Twin-Pass .023", and Twin-Pass RX Dual Access Catheters, Vascular Solutions Inc. (See FSN 21014)
NES / NESA / NTS / EPW, M.I. Tech Co., LTD (See FSN 21064)
ThermoSoft, Visiomed Technology Co., Ltd, formerly NEXMED Technology Co., Ltd (See FSN 21092)
RayStation, RaySearch Laboratories AB (See FSN 21133)
SynReam Reaming Rod ø 2.5mm, L 650mm, Synthes GmbH (See FSN 21134)
Oxivir Plus and Oxivir CE Plus, Diversey Europe Operations BV (See FSN 21421)
Avance CS2, Avance, Amingo, Datex-Ohmeda Inc (See FSN 21432)
INGEVITY™ MRI pace/sense lead, Boston scientifique CRM (See FSN 21483)
eFilm Workstation/eFilm Lite, Merge Healthcare (See FSN 21513)
Alaris VP Plus with Guardrails, CareFusion Switzerland (See FSN 21530)
Maquet Heater-Cooler Systems, Maquet (Rastatt) (See FSN 21540)
NX 3.0, Agfa HealthCare N.V. (See FSN 21616)
Apollo / DRF / EZ / EZ DRF; Clinodigit EVO, JunoDRF, Villa Sistemi Medicali SPA (See FSN 21662)
Synthes GmbH (See FSN 21706)
Devon™ Light Glove, Covidien Healthcare (See FSN 21711)
Hypodermic needle, single use, non-sterile / BD Eclipse™ Injection Needle General-purpose syringe / BD Eclipse™ Injection Needle with Luer-Lok™ Syringe, Becton Dickinson and Company (See FSN 21719)
STERRAD NX Steriliser, Advanced Sterilization Products (See FSN 21725)
Mammomat Inspiration, Siemens AG Healthcare Sector - Imaging & IT Division - Magnet Resonance (See FSN 21736)
Sterile Procedure Trays, Medline International France SAS (See FSN 21743)
Manual wheelchairs, Küschall AG (See FSN 21747)
SWITCH, Needle protected safety catheter, Vigmed AB (See FSN 21750)

Revitan® Revision Stem System, Zimmer GmbH (See FSN 21752)
BIOMESH®SOFT PROLAPS, Cousin Biotech (See FSN 21757)
Carina350, Handicare AB (See FSN 21769)
Implantable Cardiac Devices and Merlin@Home transmitter, ST Jude Medical CRMD (See FSN 21773)
DRX-Revolution Mobile X-Ray System, Carestream Health, Inc. (See FSN 21791)
Multi-length ureteral stents, Bard Medical Division (BMD) (See FSN 21794)
Coldplay CryoBalloon Focal Ablation System, C2 Therapeutics, Inc. (See FSN 21800)
Sterile Procedure Trays, Medline International France SAS (See FSN 21809)
Occlutech Occlusions-Pusher, Flex-Pusher II, Occlutech GmbH (See FSN 21819)
Integra® Cadence®Total Ankle System, Ascension Orthopedics Inc. (See FSN 21825)
Video telescope "ENDOYE HD II", 10 mm, 0° and 30°, Olympus Winter and Ibe (See FSN 21838)
Medtronic Strata™ II/Strata™ NSC Valves, Medtronic, Inc. (See FSN 21843)
Brainlab Offset Cup Impactor Universal, Brainlab AG (München) (See FSN 21847)
Scholl Oplissing voor Schimmelnagels/ Solution Mycoses des ongles, Reckitt Benckiser Healthcare Ltd (See FSN 21856)
PENTAX ULTRASOUND-VIDEOPROBRONCHOSCOPE, HOYA Corporation Medical Instrument Division (See FSN 21870)
Discovery MR450 1.5T narrow bore 1.5T non-GEM., Ge Medical Systems (See FSN 21871)
AngioJet® Ultra 5000A Console Foot Switch, Boston Scientific Corporation M (See FSN 21875)
3M™ Tegaderm™ ...(Full name see below), 3M Health Care (See FSN 21898)
StarClose SE Vascular Closure System, Abbott Vascular (USA) (See FSN 21902)
Secura Protective Cream Z10 78g (CE), Smith & Nephew (See FSN 21903)
VERSAJET II Hydrosurgery System Console, SMITH & NEPHEW Hull (See FSN 21933)
BONE WAX STICK, B. Braun Medical SA (See FSN 21944)

6 Etudes cliniques / Klinische studies

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

7 Varia

No varia

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 :

06/04/2017 : Salle/Zaal Vivaldi

à 13h00
om 13u00