

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

COMPTE-RENDU DE LA REUNION DU 07 SEPTEMBRE 2017
 VERSLAG VAN DE VERGADERING VAN 07 SEPTEMBRE 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	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 (president)	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	
Anne-Sophie Grell		Alex Rijnders	
Marc Cumps	E / V	Fien Aerts	
		Carole Absil	
Bart Mersseman	E / V	Marine Debaut	

Représentants de l'AFMPS - Vertegenwoordigers van het FAGG:

Damien Lambot	Cedric Vandenbroucke	Pieter Van De Vijver
Grégory Duby	Erina de Thaye	Ann Jans
Dejehansart Aline	Julie Roothoof	Vicky Hoymans
Kelly Decaluwé		

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 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 / Incidenten

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

- ✓ **Dossier 21191** (CCV): X7-2t Transducer (MTEE) Compact (Philips Medical)
- ✓ **Dossier 18875** (KYD): Spirotome (MedInvents)
- ✓ **Dossier 22070** (KYD): Heartmate II Left Ventrivular Assist Device (Thoratec Corporation)
- ✓ **Dossier 22340** (KYD): Scepter Balloon Catheter & Scepter XC Occlusion Balloon (MicroVention Inc)

Et / En 85 FSCA :

BrightView XCT Imaging System, Philips Healthcare Ohio (See FSN 16692)
BrightView, Philips Healthcare Ohio (See FSN 16693)
Invacare Dolomite rollators: Invacare Rea AB (See FSN 17859)

S4C OCCIPUT TORQUE WRENCH F/SET SCREW, Aesculap AG (See FSN 17868)
Fabius MRI, Drager Medical (See FSN 17992)
RotaWire Elite™ Guidewire and wireClip™ Torquer Guidewire Manipulation Device, BOSTON Scientific Corporation (See FSN 18707)
FLOW-i, MAQUET Critical Care AB (See FSN 19105)
Leica M525 OH4 / Leica M720 OH5 surgical microscope, Leica Microsystems (Scweiz) AG (See FSN 19361)
TF Adaptive Gutta Percha Point 5ize SM3 50pk, Sybron Endo (See FSN 19695)
Vacuum pump foot pump, AB Germa (See FSN 19924)
PENTARAY NAV CATHETER - PENTARAY NAV eco CATHETER, Biosense Webster Inc (See FSN 19960)
HexaPOD evo RT System / Medical Intelligence Mediz, Medical Intelligence Medizintechnik GmbH (See FSN 20155)
V-PRO® 1, V-PRO® 1 Plus, and V-PRO maX® Sterilizer, Steris Corporation (See FSN 20254)
Core Suction Irrigation Handpieces, ConMed Corporation (See FSN 20406)
Custom Procedure kits containing certain production lots of Clarify Visualization System (item code 21-345), Covidien Healthcare (See FSN 21262)
cardioLife AED, Nihon Kohden Corp. (See FSN 21354)
Imager™ II Angiographic Catheter / ARROW® International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits, BOSTON Scientific Corporation (See FSN 21618)
Extension de table orthopédique E.T.O.I.L.E, Amplitude (See FSN 21811)
Biopsy, Aspiration, Bone Marrow needles and kit, CareFusion (See FSN 22172)
Cardiovit AT-102 plus, Schiller AG (See FSN 22225)
ABSORB Bioresorbable Vascular Scaffold System ABSORB GT1 Bioresorbable Vascular Scaffold System, Abbott Vascular (USA) (See FSN 22292)
Vivid S60 / S70, GE Medical Systems Israel (See FSN 22300)
SOLUSCOPE endoscope washer-disinfector, SOLUSCOPE SAS (See FSN 22303)
sinus-SuperFlex-635, OptiMed Medizinische Instrumente GmbH (See FSN 22328)
Newport HT70 Ventilators, Newport Medical Instruments, Inc. (See FSN 22357)
Dolphin Inflation Device/Caliber Inflation Device, Perouse Medical (See FSN 22361)
Pulsante SPG Microstimulator System, Autonomic Technologies, Inc. (See FSN 22377)
ARTIS 230V, EVOSYS 230V, ARTIS AFBK, ARTIS 230V Physio, ARTIS 230V Physio LP, ARTIS AFBK Physio, ARTIS 230V LP, Gambro Dasco (See FSN 22410)

Pedicle Access Kit (PAK) Needles, Medtronic Sofamor Danek (See FSN 22536)
NavLock™ Tracker (part of below NavLock™ instrument sets and kits), Medtronic Navigation (See FSN 22612)
Various Unomedical High Concentration Oxygen Masks, Unomedical Inc (See FSN 22637)
AXIOM Iconos R100_B, Siemens AG Healthcare Sector - Imaging & IT Division - Magnet Resonance (See FSN 22679)
Vitality Spinal Fixation System, Zimmer Inc (See FSN 22680)
OEC Elite, GE OEC Medical Systems, Inc (See FSN 22687)
RADspeed Series (Pro/CH-200/CH-200M), Shimadzu Corp. (See FSN 22700)
MiniMed 640G Insulin Pump, MEDTRONIC MINIMED. (See FSN 22705)
DRX-Revolution Mobile X-Ray System, Carestream Health, Inc. (See FSN 22707)
AXS Universal Aspiration Tubing, Medela AG (See FSN 22737)
IntelliVue NMT Patient Cable, Philips Healthcare (See FSN 22738)
RF IK II, RF IK II M coat, Glidesheath Slender, Terumo Corporation TOKYO (See FSN 22750)
Infusor - Multirate and Regional Analgesia, Baxter Healthcare (See FSN 22774)
Zimmer Plates and Screws, Zimmer Universal Locking, Zimmer Inc (See FSN 22781)
GAMMA AROMA® PATCH / AROMA PATCH PETIT FORMAT MULTI-ZONES, GRAND FORMAT MULTI-ZONES, CEINTURE, RECHARGE CEINTURE, Jiangsu Procinve Jianerkang Medical Dressing Co., Ltd (See FSN 22788)
Ophthalmic Sterile Procedure Trays containing Needles 25G Orange following a supplier change, Medline International France SAS (See FSN 22790)
Artis Systems, Siemens AG (See FSN 22803)
Astral 100, Astral 100SC, Astral 150, ResMed Ltd (See FSN 22810)
Sharesource Connectivity Platform for use with the Homechoice Claria APD System, Baxter Healthcare (See FSN 22813)
CF-Y0067-L, Olympus medical Systems Corporation (See FSN 22814)
syngo Imaging, syngo.plaza, syngo Dynamics, syngo Imaging XS, MagicLink A, syngo Workflow MLR (44087), syngo Workflow SLR (44087), syngo.via (57812), syngo.via ProtoNeo(57812), Siemens AG (See FSN 22817)
Fujifilm FDR Visionary Suite, Shimadzu Corp. (See FSN 22818)
Acculis Accu2i pMTA Applicator, AngioDynamics, Inc. (See FSN 22820)
Diagnostic Ultrasound System, Toshiba Medical Systems Corporation (See FSN 22825)
Umonium38 Neutralis Spray, Huckert's International SPRL (See FSN 22842)

Red Sexp Dstl Fem 19CM LT Assy, Biomet Orthopaedics Inc. (See FSN 22843)
Encore™ 26 Inflation Device, BOSTON Scientific Corporation (See FSN 22856)
HexaPOD evo RT System / Medical Intelligence Mediz, Medical Intelligence Medizintechnik GmbH (See FSN 22866)
AFX EndoVascular AAA System, Endologix International Holdings B.V. (See FSN 22871)
SONIC microcathéter, Balt Extrusion (See FSN 22895)
Zenith Alpha™ Thoracic Endovascular Graft, William Cook Europe ApS (See FSN 22909)
SPY-PHI Drape, Guangzhou Fortunique Limited (See FSN 22932)
syngo Workflow MLR Portal Radiologist, Siemens AG (See FSN 22934)
MOSAIQ, Impac Medical Systems, Inc (See FSN 22950)
SoKINOX/SERViNO, MAQUET Critical Care AB (See FSN 22967)
NovoPen® Echo® and NovoPen® 5, Novo Nordisk A/S (See FSN 22982)
JTS Grower Drive Unit, Stanmore Implants Worldwide Ltd (See FSN 23003)
Heron, R82 A/S (See FSN 23027)
Acumed Kickstand Post ; 2.8mm Locking Drill Guide, Acumed LLC (See FSN 23035)
Persona Partial Knee Guide Size 8, Zimmer Inc (See FSN 23071)
Euphora Rapid Exchange Balloon Dilatation Catheter / Solarice Rapid Exchange Balloon Dilatation Catheter, Medtronic Inc. Minneapolis (See FSN 23076)
optimys stem lat. TAV 7 uncem., Mathys Ltd Bettlach (See FSN 23104)
AIRO Mobile CT System, Mobius Imaging, LLC (See FSN 23107)
LIFEPAK® 15 MONITOR/DEFIBRILLATOR, Physio-Control (See FSN 23112)
Percuvance® Percutaneous Surgical System, Teleflex Medical (See FSN 23124)
Pneumo-Kryosonde; flexibel / Pneumo-Cryoprobe; flexible, ERBE Elektromedizin GmbH (See FSN 23127)
PLATINIUM / PLATINIUM 4LV CRT1744, Sorin Group Italia Srl (See FSN 23145)
balanSys RP Tibial Plateaus TiNbN cem., Mathys Ltd Bettlach (See FSN 23152)
HomeChoice Pro; Homechoice Claria APD Cyclor, Baxter Healthcare (See FSN 23167)
ReNew Reusable Laparoscopic Instrument Tips, Microline Surgical Inc. (See FSN 23168)
POLARSTEM Cardan for 21000438, Smith & Nephew Orthopaedics Ltd (See FSN 23171)
Various Stryker Hip products, Howmedica Osteonics Corporation (See FSN 23174)
CORAIL® COXA VARA HIGH OFFSET STEM, DePuy France (See FSN 23192)
Fogarty Adherent Clot Catheter, Edwards Lifesciences (See FSN 23202)

PUBLIC

DG POST/matériovigilance

Extracorporeal Tubing Set containing the Over-pressure Safety Valve, HMT Medizintechnik GmbH (See FSN 23242)
Arctic Sun® 5000 Temperature Management System, Medivance, Inc (See FSN 23251)
Central Venous Catheter Set Heparin Coated Triple Lumen Polyurethane / Central Venous Catheter Set Triple Lumen Polyurethane / Central Venous Catheter Tray Triple Lumen Polyurethane, Cook Incorporated (See FSN 23267)

PUBLIC

6 Etudes cliniques / Klinische studies

15 études cliniques ont été présentées à la Commission

15 Klinische studies werden gepresenteerd tijdens de Evaluatie Commissie

7 Varia

HeartMate III

La réunion s'est clôturée à 14h10

De vergadering wordt voor gesloten verklaard om 14h10

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 :

05/10/2017 : Salle/Zaal Vivaldi

à 13h00
om 13u00