

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

COMPTE-RENDU DE LA REUNION DU 04 JUIN 2015  
VERSLAG VAN DE VERGADERING VAN 04 JUNI 2015

**Liste de présence – Aanwezigheidslijst**

<b>Membres Effectifs Effectieve leden</b>	P / A = Présent / Aanwezig E / V = Excusé / Verontschuldigd	<b>Membres suppléants Plaatsvervangende leden</b>	P / A = Présent / Aanwezig E / V = Excusé / Verontschuldigd
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	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		Fien Aerts	
		Carole Absil	
Bart Mersseman	P / A	Marine Debaut	E / V

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

Vandenbroucke Cédric	Van De Vijver Pieter
Decaluwé Kelly	Jans Ann
Roothoofit Julie	Demonceau Caroline
Dejéhansart Aline	

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**

Approuvé / goedgekeurd

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

Approuvé / goedgekeurd

**3 Conflits d'intérêt / Belangenconflict**

Non / Neen

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

3 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 3 dossiers ont été présentés oralement durant cette Commission d'Evaluation

**Dossier 17167:** SJM Trifecta Valve (St. Jude Medical)

**Dossiers 17231 et 17230:** Intra-aortic balloon catheter (Arrow International)

**5 Incidents**

0 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 0 dossiers ont été présentés oralement durant cette Commission d'Evaluation

## 41 FSCA sont soumis à la Commission / 41 FSCAs werden voorgelegd aan de Commissie

Vitreia Enterprise Suite, Vitrea, VitreaAdvanced, VitreaCore (VitalConnect), Vitrea fX, and VitreaLT, Vital Images, Inc. (See FSN 12724)
neoBLUE Phototherapy LED Replacement Board Kit, Natus Medical Inc (See FSN 16670)
Dialog+, B. BRAUN AVITUM AG (See FSN 16728)
Babytherm, Dräger Medical (See FSN 16050)
Ysio S und Ysio , Ysio Max, Siemens AG Healthcare Sector - Imaging & IT Division - Magnet Resonance (See FSN 15469)
Colleague Single and triple Channel Mono Chrome Pump English v1.7Colleague Single and triple Channel Mono Chrome Pump Swedish v1.7Colleague Single and triple Channel Mono Chrome Pump German v1.7Colleague Single and triple Channel Mono Chrome Pump French v1.7Colleague Single and triple Channel Mono Chrome Pump Italian v1.7Colleague Single and triple Channel Mono Chrome Pump Spanish v1.7Colleague Single and triple Channel Mono Chrome Pump Portuguese v1.7Colleague Single and triple Channel Mono Chrome Pump Dutch v1.7Colleague Single and triple Channel Mono Chrome Pump Polish v1.7Colleague Single and triple Channel Mono Chrome Pump Czech v1.7Colleague Single and triple Channel Mono Chrome Pump Slovak v1.7Colleague Single and triple Channel Mono Chrome Pump Hungarian v1.7Colleague Single and triple Channel Mono Chrome Pump Romanian v1.7Colleague Single and triple Channel Mono Chrome Pump Bulgarian v1.7Colleague Single and triple Channel Mono Chrome Pump Greek v1.7Colleague Single and triple Channel Mono Chrome Pump Turkish v1.7Colleague Single and triple Channel Mono Chrome Pump Arabic v1.7Colleague Single and triple Channel Mono Chrome Pump Hebrew v1.7Colleague Single and triple Channel Mono Chrome Pump Russian v1.7Colleague Single and triple Channel Mono Chrome Pump Ukrainian v1.7Colleague Single and triple Channel Mono Chrome Pump Belarusian v1.7Colleague Single and triple Channel Mono Chrome Pump Serbian v1.7Colleague Single and triple Channel Mono Chrome Pump Croatian v1.7Colleague Single and triple Channel Mono Chrome Pump Slovenian v1.7Colleague Single and triple Channel Mono Chrome Pump Macedonian v1.7Colleague Single and triple Channel Mono Chrome Pump Bosnian v1.7Colleague Single and triple Channel Mono Chrome Pump Montenegrin v1.7Colleague Single and triple Channel Mono Chrome Pump Albanian v1.7Colleague Single and triple Channel Mono Chrome Pump Bulgarian v1.7Colleague Single and triple Channel Mono Chrome Pump Romanian v1.7Colleague Single and triple Channel Mono Chrome Pump Serbian v1.7Colleague Single and triple Channel Mono Chrome Pump Croatian v1.7Colleague Single and triple Channel Mono Chrome Pump Slovenian v1.7Colleague Single and triple Channel Mono Chrome Pump Macedonian v1.7Colleague Single and triple Channel Mono Chrome Pump Bosnian v1.7Colleague Single and triple Channel Mono Chrome Pump Montenegrin v1.7Colleague Single and triple Channel Mono Chrome Pump Albanian v1.7Colleague Single and triple Channel Mono Chrome Pump
EmbryoScope, Unisense FertilTech A/S (See FSN 15598)
On-Board Imager® (OBI), Varian Oncology Systems (USA) (See FSN 15133)
See list attached to customer letter, Medtronic Navigation (See FSN 15499)
MX 16-slice, Philips and Neusoft Medical Systems Co., Ltd. (See FSN 16414)
Hudson RCI® Sheridan/CF® Cuffed Tracheal Tube, Teleflex medical (See FSN 16594)
MobileDiagnost wDR, Philips Medical Systems DMC GmbH (See FSN 15810)
Spirotome, Medinvents NV (See FSN 16228)
HeartStart MRx Defibrillator/Monitor, Philips Medical systems (Andover) (See FSN 16764)
Nanostim™ Leadless Pacemaker, St. Jude Medical (See FSN 16757)
Vapotherm Precision Flow Disposable Patient Circuit / Disposable Patient Circuit Delivery Tube (DPC), Vapotherm, Inc. (See FSN 16084)
Drill set long, drill stop compatible for D 4.8mm, Institut Straumann AG (See FSN 16478)
Proclear toric (also including branded variants), CooperVision Manufacturing Limited (See FSN 16299)
EndoWrist® One Vessel Sealer Instruments- EndoWrist® Vessel Sealer instruments, Intuitive Surgical (See FSN 17211)
UNIVERSAL Modular Electric/Battery Double Trigger Handpiece, ZIMMER SURGICAL SA (See FSN 16275)
DAR Breathing System, Mapleson B and C config, Covidien llc (See FSN 16462)
DRX-Revolution Mobile X-Ray System, Carestream Health, Inc. (See FSN 16633)
Biomedics toric (and branded variants), CooperVision Manufacturing Limited (See FSN 16525)
Luminos dRF / Luminos dRF Max, Siemens AG Healthcare Sector - Imaging & IT Division - Magnet Resonance (See FSN 16058)
EPIQ 5, Philips Health Care (See FSN 16716)
B500, 490E32=00000_K; B500-S, 490E32=60000_K; B600, 490E32=10000_K; C1000-DS, 490E68=00000_K, OTTO BOCK Mobility GmbH (See FSN 16959)
Zenith Alpha™ Thoracic Endovascular Graft, William Cook Europe ApS (See FSN 17069)
da Vinci Xi? Surgical System, Intuitive Surgical (See FSN 17398)
Bipolar insert BISON, grasping forceps fenestrated / GRASPING FORCEPS FENESTRATED, ONLY WL 330 MM, Ø 5, Rudolf Medical GmbH & Co. KG (See FSN 16976)
Passero-18, Biotronik Ag (See FSN 17164)
Terumo® Radifocus Optitorque Catheter, Terumo Europe NV (See FSN 17460)
Xcela PICC & BioFlo PICC, Navilyst (See FSN 16986)
Persona-Constrained Tibial Artic. Surf. Prov. Shim, Zimmer Inc (See FSN 17000)
Leo / Comet / Orion, Chien Ti Enterprises Co. Ltd. (See FSN 17172)
ADAC Vertex Plus, CARDIO and SolusADAC V60ADAC C60, Philips Healthcare Ohio (See FSN 17445)
MEVATRON, PRIMUS, ONCOR and ARTISTE, Siemens AG Healthcare, Geschäftsgebiet Radiation Oncology (See FSN 16900)
• VYGON Filtraflux + SoftFlex• VYGON HEPA Filter Humidifier + SoftFlex• VYGON Softflex• BOSS SYSTEMS Soft Flex• MAQUET Servo Humidifier 163• MAQUET Servo Humidifier 163
Artis/Evosys machines, Gambro Dasco (See FSN 16872)
GentleLase Pro, CANDELA CORPORATION (See FSN 17256)
HeartWare Ventricular Assist System, HeartWare Inc (See FSN 16883)
Bard Max-Core Disposable Core Biopsy Instrument, Bard Peripheral Vascular (BPV) (See FSN 17569)

## 6 Etudes cliniques / Klinische studies

4 études ont été présentées / 4 studies werden gepresenteerd

**PUBLIC**

## 7 Varia

- 1- NuSurface kunstmeniscus studie (firma Active Implants)  
Er is een teleconferentie geweest over deze implantaten.

La réunion s'est clôturée à 13h45

De vergadering wordt voor gesloten verklaard om 13u45.

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 :*

**02/07/2015 : Salle/Zaal Marco Polo**

à 13h00  
*om 13u00*