

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

**COMPTE-RENDU DE LA REUNION DU 03 SEPTEMBRE 2015  
VERSLAG VAN DE VERGADERING VAN 03 SEPTEMBER 2015**

**Liste de présence – Aanwezigheidslijst**

<b>Membres Effectifs Effectieve leden</b>	<b>P / A = Présent / Aanwezig E / V = Excusé / Verontschuldigd</b>	<b>Membres suppléants Plaatsvervangende leden</b>	<b>P / A = Présent / Aanwezig E / V = Excusé / Verontschuldigd</b>
Els Tuyls		Marianne Van Malderen	P/A
Awatif Jebari	P/A	Emmanuelle Gay	
Maries Merken		Rita Cornélis	
Guibert Crèvecoeur		Jean-Claude Mignolet	
Isabelle De Pau ad it. Tom Clarijs + Maboge Claude	E/V	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	
Anne-Sophie Grell		Alex Rijnders	
Marc Cumps		Fien Aerts	
		Carole Absil	E/V
Bart Mersseman		Marine Debaut	P/A

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

Vandenbroucke Cédric	Lambot Damien	Jebari Awatif
Decaluwé Kelly	Jans Ann	Van De Vijver Pieter
Roothoofthof Julie	Watteeuw Sibylle	Everaert Erik
Vanackere Sebastien	Delplace Elodie	Schuyvinck Anne
Demonceau Caroline		

Le président ouvre la réunion à 13h10. Le quorum n'est pas atteint.

*De voorzitter opent de vergadering om 13u10. 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**

0 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 0 dossier a été présenté oralement durant cette Commission d'Evaluation

**5** **Incidents**

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

**Dossier 17428**: HeartMate II Left Ventricular Assist Device (Thoratec Corp)

**Dossier 17658**: Evolution Everolimus-Eluting Coronary Stent System / SYNERGY Everolimus-Eluting Platinum Chromium Coronary Stent System (Boston Scientific Corporation)

**Dossier 17730** : Fresenius Kabi - Feeding tube Fr. 8, 270cm, LL

**Dossier 17980**: Fresenius Kabi - Freka Intestinal tube 9 FR for PEG FR 15

45 FSCA sont soumis à la Commission / 45 FSCAs werden voorgelegd aan de Commissie

1. Dossier 13057: iPlan RT Dose, BrainLAB AG
2. Dossier 14053: DENTAL LIGHT Type LOLé2, DEGRÉ K

3. Dossier 15171: MONNAL T50, T40, AIR LIQUIDE MEDICAL SYSTEMS
4. Dossier 15346: Carescape Patient Data Module, GE Medical Systems Information Technologies
5. Dossier 15415: DF53C GS corPatch easy pre-connected, Leonard Lang GmbH
6. Dossier 15829: Invacare REA Focus, Spirea and Spin-X, Invacare Rea AB
7. Dossier 16247: Artis Zeego ; Artis zee, Siemens AG
8. Dossier 16318: Inflation device DOLPHIN- Caliber Inflation device, Perouse Medical
9. Dossier 16439: Carescape Patient data Module, GE Medical Systems Information Technologies
10. Dossier 16632: corPatch-clip Neonaten,-easy Pedriatic,-easy neona Leonhard lang Medizintechnik GmbH
11. Dossier 16679: BRONCHIAL DOUBLE LUMEN TUBE SET (LEFT), STERILE  
BRONCHIAL DOUBLE LUMEN TUBE SET (RIGHT), STERILE  
BRONCHIAL ONE LUMEN TUBE - LEFT  
BRONCHIAL ONE LUMEN TUBE - RIGHT  
CARLENS BRONCHIAL DOUBLE LUMEN TUBE SET (LEFT), STERILE  
TRACHEOPART SET (LEFT), STERILE  
TRACHEOPART SET (RIGHT), STERILE  
WHITE BRONCHIAL DOUBLE LUMEN TUBE SET (RIGHT), STERILE, Teleflex Medical
12. Dossier 16815: syngo.plaza, Siemens AG
13. Dossier 16886 : 551.31 Filtraflux + Softflex, 551.33 Hepa Filter Humidifier + Softflex, 7 + Sft Triplus, 7+Sft, 805.02 Soft – Flex, Fh Soft, Fh With Soft - Flex And Swivel Mounted, Humid Vent Filter Compact S With Soft Flex/ Swivel Mounted, Humid Vent Filter Compact S With Soft Flex/Swivel Mounted With Tethered Cap, Humid-Vent Filter Compact S With Soft - Flex / Elbow Mounted, Humid-Vent Filter Light S With Soft Flex/Swivel Mounted, Sfh173 Maquet, Sh163 Maquet, Soft Flex Tube, Soft Flex With Cap Mounted, Soft Flex With Double Swivel Sterile, Soft Flex With Swivel Connector, Soft-Flex With Double Swivel, Soft-Flex With Elbow, Vygon Fh+Sft With Elbow Connector Nm 551.61, Inmed Manufacturing Sdn Bhd

14. Dossier 16967: BIRMINGHAM HIP Resurfacing System (BHR), Smith & Nephew Orthopaedics Ltd
15. Dossier 17068: LMA® Supreme (New Cuff) Size 5, The laryngeal Mask Company
16. Dossier 17083: MultiDiagnost Eleva FD, Philips Medical Systems Nederland BV
17. Dossier 17151: Puritan Bennett 980 Ventilator, Covidien Healthcare
18. Dossier 17187: SOLUSCOPE SERIE 4 PA IT Soluscope, SOLUSCOPE SAS
19. Dossier 17249 : Nellix EndoVascular Aneurysm Sealing System, Endologix, Inc
20. Dossier 17294: Pedicle Awl 4.0mm w/Silicone Handle / Pedicle Awl 4.0mm w/Canevasit Handle, Synthes GmbH
21. Dossier 17363: Vacuum Source Tubing Set for EndoWrist Stabilizer, Microtek Medical Inc.
22. Dossier 17366: Juno DRF, Philips Medical Systems DMC GmbH
23. Dossier 17378: Persona Anterior Referencing Sizer - Locking Boom, Zimmer Inc
24. Dossier 17543: ETHICON VICRYL™ Suture, Johnson & Johnson Medical nv
25. Dossier 17585: Accu-Chek Spirit Combo; Accu-Chek Spirit, ROCHE DIAGNOSTICS GMBH
26. Dossier 17654 : Freka Connect ENLock 60ml, Fresenius Kabi Medical Care AG
27. Dossier 17660: EPIQ 5, Philips Health Care
28. Dossier 17682: Minisart, SARTORIUS STEDIM BIOTECH
29. Dossier 17686: Terumo Radifocus Guide Wire M, Terumo Europe
30. Dossier 17711: Carescape Monitor Bx50, Ge Healthcare Finland
31. Dossier 17728: EXPEDIUM® Spine System, DePuy Spine
32. Dossier 17743: AFFINITI 70, Philips Health Care
33. Dossier 17759: Hamilton Medical Infant Flow Sensor, single use, Hamilton Medical AG
34. Dossier 17767: Pulsar-18 & Pulsar-35 (200mm length only), Biotronik AG
35. Dossier 17782: Catalys Precision Laser System, OPTIMEDICA CORPORATION
36. Dossier 17931: Guide Wire Diameter 2.8mm, Length 180mm, w/thread, Synthes GmbH
37. Dossier 17939: Composelect, compoflex, compoflow, Fresenius Kabi Medical Care AG
38. Dossier 17943: Deltastream MDC Battery Pack und A active Battery Pack, Medos Medizintechnik AG

39. Dossier 17948: Compoflex® 4F & Composelect® 4F, Fresenius Kabi Medical Care AG
40. Dossier 17959: Merit Prelude Sheath Introducer, Merit Medical Systems Inc
41. Dossier 17971: IPS e.max Ceram, IVOCLAR VIVADENT AG
42. Dossier 18013 : D-Fend/D-Fend+ Water Traps, Ge Healthcare Finland
43. Dossier 18080: RHK Knee Femoral Component, Biomet UK Ltd
44. Dossier 18120: Reamer/Irrigator/Aspirator (RIA), Synthes GmbH
45. Dossier 18267: EU-04041-HP EU Special Order Product, EU-04041-HPMSB Arrow® Pressure Injectable PICC Kit with Blue FlexTip® Catheter, EU-04052-HPMSB Arrow® Pressure Injectable Two-Lumen PICC Kit with Blue FlexTip® Catheter, EU-05041-HPMSB Arrow® Pressure Injectable PICC Kit with Blue FlexTip® Catheter, EU-05052-HPMSB Arrow® Pressure Injectable Two-Lumen PICC Kit with Blue FlexTip® Catheter, EU-05541-HP EU Arrow Select Kits, EU-05541-HPMSB Arrow® Pressure Injectable PICC Kit with Blue FlexTip® Catheter, EU-05552-HPMSB Arrow® Pressure Injectable Two-Lumen PICC Kit with Blue FlexTip® Catheter, FR-04041 EU Arrow Select Kits, FR-04041-CF EU Arrow Select Kits, FR-05041 EU Arrow Select Kits, FR-05041-CF EU Arrow Select Kits, FR-05541-CF EU Arrow Select Kits, UK-05041-HPMIN EU Arrow Select Kits, ARROW International

## **6 Etudes cliniques / Klinische studies**

15 études ont été présentées / 15 studies werden gepresenteerd

## **7 Varia**

- 1- NuSurface kunstmeniscus studie (firma Active Implants)  
The notified body heeft ons gemeld dat de CE markering in orde is.  
Dit dossier werd geëvalueerd door verschillende experts.
- 2- RCT (présentation par Anne Schuyvinck et Erik Everaert)  
Liste des implants à enregistrer pour la traçabilité

**PUBLIC**

**La réunion s'est clôturée à 14h30**  
**De vergadering wordt voor gesloten verklaard om 14h30**

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 :*

**01/10/2015 : Salle/Zaal Vivaldi**

à 13h00  
*om 13u00*