

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

**COMPTE-RENDU DE LA REUNION DU 02 AVRIL 2015
VERSLAG VAN DE VERGADERING VAN 02 APRIL 2015**

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	P / A
Maries Merken		Rita Cornélis	
Guibert Crèvecoeur		Jean-Claude Mignolet	
Isabelle De Pau ad it. Tom Clarijs	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	E / V	Fien Aerts	
		Carole Absil	E / V
Bart Mersseman	E / V	Marine Debaut	P / A

Représentants de l'AFMPS - Vertegenwoordigers van het FAGG

Vanackere Sebastien	Watteeuw Sibylle	Debeuf Hélène
Lambot Damien	Jans Anne	Broekaert Annick
Badisco Liesbeth	Eglen Steve	Verhoye Ann
Roothoof Julie	Demonceau Caroline	Van Der Linden Davy
Decaluwé Kelly		
Driesmans Christophe		

PUBLIC

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**

Goedgekeurd mits toevoeging van 4 variapunten:

- Terumo
- ALCL
- Mycobacterium
- NuSurface studie

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

Approuvé / goedgekeurd

3 **Conflits d'intérêt / Belangenconflict**



Fien Aerts membre de la Commission peut avoir un conflit d'intérêts avec Terumo.

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 16778: SJM Trifecta Valve (St. Jude Medical)

Dossier 16755: Information Center Client REL M.0 (Philips Medical Systems)

Dossier 16988: Accu-check Spirit Combo (Roche Diagnostics)

5 **Incidents**

1 dossier werd mondeling gepresenteerd tijdens deze Evaluatiecommissie / 1 dossier a été présenté oralement durant cette Commission d'Evaluation

Dossier 15236: Heartstart XL+ (Philips Medical Systems)

83 FSCA sont soumis à la Commission / 83 FSCAs werden voorgelegd aan de Commissie

HOSPAL CARTRIDGE C3, Gambro Dasco (See FSN 4499)
Micrus Watusi Guide Wire, Micrus Endovascular (See FSN 4506)
PT2 Guide Wire, Boston Scientific Corporation (See FSN 4514)
LIFEPAK 20 defibrillator/monitor, Medtronic Emergency Response Systems (See FSN 4519)
Namic Fluid Injection Line, Boston Scientific Corporation (See FSN 4532)
APS III and MERLIN PCS in Identity SR 5172, Identity DR 5370 and Identity XL DR 5376, ST Jude Medical (See FSN 4571)
DatachTip Endoscopic Multiple Use Graspers & ConMed Disposable Graspers & Dissectors, ConMed Corporation (See FSN 4587)
Sealguard, TYCO HEALTHCARE MALLINCKRODT (See FSN 4588)
Interlocking Detachable Coils for occlusion (IDC), Boston Scientific Corp (See FSN 4602)
Orthopaedic implants, Biomet (See FSN 4626)
Tube Cover, Camera Drape, Mölnlycke Health Care AB (See FSN 4651)
LEGENDAIR Pressure and Volume Ventilator, AIROX S.A. (See FSN 4652)
Preface Sheath, Biosense Webster (See FSN 4656)
Acclaim HC401 Nasal Mask, Fisher & Paykel Healthcare Ltd (See FSN 4661)
ConMed Linvatec UltraPower Bur Products and ConMed Linvatec E9000 Bur Products, Sterile, Single-use in Pouches, ConMed Linvatec (See FSN 4696)
20 Gauge Millennium Lightning High-Speed Vitrectomy Cutter Tip and Pack, Bausch & Lomb - Optics center (See FSN 4759)
TSV 25 Gauge High-Speed Cutter and TSV 25 Gauge High-Speed Posterior Vitrectomy Pack, Bausch & Lomb - Optics center (See FSN 4851)
Introcann Stylet, Braun Medical (See FSN 4875)
Carotid Wallstent Monorail Carotid Endoprosthesis, Boston Scientific Ireland Ltd. (See FSN 4888)
SilverSpeed Guidewire, Ev3 Neurovascular (See FSN 4928)
ConMed Linvatec Medical Devices Packaged within certain Peel Pouch Sterile Packages, ConMed Linvatec (See FSN 4944)
FOLEY Siliconized Catheter, sizes: 6Ch/Fr, 8Ch/Fr, 10Ch/Fr,, Unomedical A/S (See FSN 5073)
MiniMed Paradigm, MEDTRONIC MINIMED. (See FSN 5198)
LEGENDAIR, AIROX S.A. (See FSN 5243)
Distractor Frame, Strycker (See FSN 5249)
Rad 9 Pulse Oximeter, Masimo (See FSN 5286)
SUPPORTAIR, SMARTAIR plus, LEGENDAIR, AIROX S.A. (See FSN 5301)
Morcellator Blade, laparoscopic, transvaginal, laparoscopic, 12 mm for use with RotoCut G1 system, Karl Storz GmbH & Co. KG (See FSN 5347)
Frazier and Poole Suction Instruments, ConMed Corporation (See FSN 5349)
Volcano s5 Imaging System, Volcano Corporation (See FSN 5352)
Multi Parameter Monitor, CU Medical Systems, Inc (See FSN 5375)
Anlegezange N.Caspar F.STD Clips Ger./Anlegezange N.Caspar F. Miniclips Ger. (Caspar Applier for Yasargil mini titanium aneurysm clips & Caspar Applier for Yasargil Subclavian Clamp, Kimal plc (See FSN 5486)
Umbilical cord clamp, Changshu Senlin Medical Appliance Co., Ltd (See FSN 5488)
Stretcher Brake Cam, Stryker Medical Kalamazoo (See FSN 5573)
Pulmonetic Systems Models LTV 1000, 950, 900 and 800 ventilators, Cardinal Health/Pulmonetic Systems (See FSN 5752)
VAMP Jr Pediatric disposable Pressure Transducer, Edwards Lifesciences (See FSN 5852)
Multifiltrate Kit, Multifiltrate Cassette, Fresenius Medical Care AG (See FSN 5974)
CARMEDA -coated cardiopulmonary bypass products/ TRILLIUM FSN, MEDTRONIC Inc. (See FSN 5996)
NexGen Complete Knee Solution Articular Surface Insertion Instrument, Zimmer Inc (See FSN 5997)
Standard SlingBar 450, Hill-Rom (See FSN 13214)
iViewC, Elekta BMEI (Beijing) Medical Equipment Co. Ltd (See FSN 13593)
Vector TAS Screw (8mm), Ormco Corporation (See FSN 13679)
See list attached, Biomet (See FSN 13894)
Desktop pro, Elekta Ltd (See FSN 14483)
MRP-TITAN/KAM-TITAN-Instrumentation / Torsion-free pretensioning device, PETER BREHM Chirurgie-Mechanik e.K. (See FSN 14858)
550 TxT™ Treatment Table, Siemens AG Healthcare, Geschäftsgebiet Radiation Oncology (See FSN 15194)
A200; 490E46=00000_C/ Skipipi/ Skipipi Plus; 490E55=00000_K, OTTO BOCK Mobility GmbH (See FSN 15329)
Catheter veineux central injectable sous pression - Produit de catheterisme veineux central multi-lumieres - Produit de catheterisme veineux central multi-lumieres
Compact Airway Modules: E-CaiO-00 E-CaiOV-00 E-CaiOVX-00 E-CO-00 E-COV-00 and E-COVX-00, Ge Healthcare Finland (See FSN 15711)
CARDIOXYL®, CARDIOFLON® EvolutionSURGIKIT® (containing the two products above), Laboratoires Peters Surgical (See FSN 15721)
CARESCAPE Monitor B850, Ge Healthcare Finland (See FSN 15783)
CARESCAPE Monitor B650, Ge Healthcare Finland (See FSN 15784)
CARESCAPE Monitor B450, Ge Healthcare Finland (See FSN 15785)
Gel-E Donut and Squishon 2, Philips Medical systems (Andover) (See FSN 15875)
OEC®9900 Elite, GE Healthcare USA (See FSN 15883)
medi Clutch Lock, medi Modular Clutch Lock, Medi GmbH and Co KG (See FSN 15954)
Getinge 46 series, Getinge Disinfection AB (See FSN 16001)
TomoTherapy Treatment System, Accuray Incorporated (See FSN 16006)
SYNCHROMED II implantable drug pumps, Medtronic Inc. (See FSN 16310)
Persona Distal Valgus Alignment Guide, Zimmer Inc (See FSN 16418)
THERMOCOOL™SMARTTOUCH Catheter, Biosense Webster Inc (See FSN 16431)
Advantage XP Male Sling System, American Medical Systems Inc. (See FSN 16434)
Infant Warmer, Fisher & Paykel Healthcare Ltd (See FSN 16508)
MiniMed Silhouette™ and Sure-T™ infusion sets, UnoMedical A/S - Lejre (See FSN 16515)
TITAN operating table, Trumpf Medizin Systeme GmbH (See FSN 16518)
comfort?, comfort? short et contact? detach / Silhouette / ACCU-CHEK TenderLink / ACCU-CHEK / Sure-T / Silhouette Paradigm / Sure-T Paradigm, Unomedical (See FSN 16616)
Affinis Inverse & Fracture ceramic components, Mathys Ltd Bettlach (See FSN 16616)
Licox Brain and Recon Tissue Oxygen Monitoring, GMS, Gesellschaft für medizinische Sondentechnik mbH (See FSN 16640)
MIT-H® Pfanneneinschlaginstrument, Waldemar Link GmbH & Co (See FSN 16651)
THERMOCOOL ? SMARTTOUCH? SF CATHETER, Biosense Webster Inc (See FSN 16664)
Vena Cava Filter Sets, William Cook Europe ApS (See FSN 16690)
Cannulated Screw Ø 3.5 mm, self-dr 40/13 mm, Titan, Synthes GmbH (See FSN 16697)
PLATINUM (APELEM), BACCARA Platinum (APELEM), PLATINUM dRF (APELEM), BACCARA Platinum dRF (APELEM) and AGIL FPD (GILARDONI), APELEM (See FSN 1685)
Quadrox-ID adult/small adult / HLS Set Advanced 7.0, Maquet Cardiopulmonary AG (See FSN 16860)
Steuereinheit des NEURO TRONIC Kniegelenksystems / Controller for NEURO TRONIC knee joint system, Fior & Gentz GmbH (See FSN 16891)
Pre-Loaded Barricaid® Delivery Tool, Intrinsic Therapeutics (See FSN 16928)
Ebb Complete Tamponade System, Clinical Innovations (See FSN 16966)
GE MR Systems - refer to comments for product list, GE Medical Systems Information Technologies (See FSN 17089)
Cardiosave Hybrid Intra-Aortic Balloon Pump, Maquet Cardiovascular LLC (See FSN 17094)
MIS DuploSpray Regulator, Micromedics, Inc (See FSN 17112)
Titan™ and Titan™ 360 Stabilizer Attachments, Terumo Cardiovascular Systems (See FSN 17156)
FlexCath® Select Steerable Sheath, Medtronic CryoCath (See FSN 17225)

PUBLIC

6 Etudes cliniques / *Klinische studies*

5 études ont été présentées / 5 studies werden gepresenteerd

7 Varia

- 1- ALCL (Anaplastic large cell lymphoma)
- 2- NuSurface kunstmeniscus studie (firma Active Implants)
- 3- Mycobacterium
- 4- Terumo

La réunion s'est clôturée à 14h30

De vergadering wordt voor gesloten verklaard om 14u30.

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 :

02/04/2015 : Salle/Zaal Vivaldi

à 13h00
om 13u00