

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

COMPTE-RENDU DE LA REUNION DU 01 FEVRIER 2018  
VERSLAG VAN DE VERGADERING VAN 01 FEBRUARI 2018

**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	E / V
Awatif Jebari		Emmanuelle Gay	P / A
Maries Merken		Rita Cornélis	
Guibert Crèvecoeur		Jean-Claude Mignolet	
Claude Maboge ad it. Isabelle De Pau ad it. Tom Clarijs	P / A	Annie Vanderlinck	
Guido Van Nooten	P / A (president)	Yves Taeymans	
Hein Heidebüchel		Rik Willems	
Kristel De Vogelare		Daniel Mojet	
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	
		Carole Absil	
Bart Mersseman		Marine Debaut	

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

Cedric Vandenbroucke	Julie Roothoof	Pieter Van De Vijver
Gregory Duby	Erina De Thaye	Ann Jans
Sibylle Watteeuw	Aline Degehansart	Vicky Hoymans

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

**5 Incidents / Incidenten**

7 dossiers werden mondeling gepresenteerd tijdens deze Evaluatiecommissie / 7 dossiers ont été présentés oralement durant cette Commission d'Evaluation

- ✓ **Dossier 22877** (CCV): Trifecta™ GT Valve (Ortho Maquet)
- ✓ **Dossier 23817** (CCV): Portico (St Jude Medical)
- ✓ **Dossier 23676** (CCV): Perceval Sutureless Aortic Heart valve (LivaNova)
- ✓ **Dossier 24038** (KYD): MitraClip (Abbott Vascular)
- ✓ **Dossier 24095** (DAT): SJM Masters Series Mechanical Heart Valve (St Jude Medical)
- ✓ **Dossier 23776** (GDY): AMPLATZER Amulet (AGA Medical Corporation)
- ✓ **Dossier 24431** (GDY): AMPLATZER Amulet (AGA Medical Corporation)

Et / en 62 FSCA:

Laerdal Compact Suction Unit (LCSU4), Laerdal Medical AS (See FSN 21452)
CORFLO PEG Adapter with ENFit Connectors, CORPAK Medsystems (See FSN 21806)
Vermeiren, NV VERMEIREN (See FSN 22206)
CT Exprès 3D / 4D Temperature Maintainer model, Bracco Injengineering SA (See FSN 22339)
ACUSON S Family with SW vers. VD10A or VD10C, Siemens Medical Solutions USA, Inc. Ultrasound (See FSN 22341)
HITACHI / ARIETTA Prologue, Hitachi Aloka Medical Ltd. (See FSN 22815)
Voyager Evo Starrahmenrollstuhl / Voyager Evo rigid frame wheelchair, Otto Bock Mobility Solutions GmbH (See FSN 23074)
Datascope Intra-Aortic Balloon Pump, Datascope Corp. (See FSN 23097)
Accu-Chek® Insight, Roche Diabetes Care GmbH (See FSN 23150)
Oncentra Brachy 4.5, NUCLETRON B.V. (See FSN 23295)
SERVO-air, MAQUET Critical Care AB (See FSN 23354)
EC-3 Posterior Chamber Hydrophobic Acrylic Lens, Aaren Scientific (See FSN 23427)
Revolve™ System, LifeCell Corporation (See FSN 23515)
Taylor Spatial Frame Website Software, Smith & Nephew USA (See FSN 23616)
All artis systems with Wireless foot switch, Siemens AG (See FSN 23625)
CORONYL 8/0, SAS PETERS SURGICAL (See FSN 23739)
rHead® System Radial Head Arthroplasty / Uni Elbow, Stryker Osteosynthesis Selzach (See FSN 23744)
Abutment Screw Diamond, Integrum AB (See FSN 23783)
Nasogastric Feeding Tubes for neonates & pediatric / ENTRAL, Maxter Catheters (See FSN 23795)
CP5 CENTRIFUGAL PUMP, Sorin Group Deutschland / LivaNova (See FSN 23813)
IV Administration sets, PMH - Produtos Medico Hospitalares (See FSN 23818)
Soft suction liner 3000cc/ml (with tube / Med-Gel), Medline Industries Inc. (See FSN 23860)
ExacTrac Vero, Brainlab Sales GmbH (See FSN 23862)
ProteusONE, IBA (Ion Beam Applications) (See FSN 23866)
ACUVUE® OASYS®, ACUVUE® ADVANCE®, 1-DAY ACUVUE MOIST®, Johnson & Johnson Vision Care, Inc. (See FSN 23870)
1-DAY ACUVUE® MOIST Brand Contact Lenses, Johnson & Johnson Vision Care, Inc. (See FSN 23871)

ACUVUE® OASYS® for ASTIGMATISM with Hyrdoclear, Johnson & Johnson Vision Care, Inc. (See FSN 23873)
Persona Partial Knee Impactor Pad, Biomet Orthopaedics Inc. (See FSN 23948)
REFOBACIN PLUS BONE CEMENT / OPTIPAC 80 REFOBACIN BONE CEMENT / OPTIPAC 40 REFOBACIN BONE CEMENT / OPTIPAC 60 REFOBACIN BONE CEMENT / OPTIPAC KNEE REFOBACIN PLUS BONE CEMENT / REFOBACIN BONE CEMENT / BIOMET orthopaedics (See FSN 23976)
SynchroMed® II Implantable Drug Pumps, Medtronic Inc. (See FSN 23986)
SmartBase, Autochair Ltd (See FSN 23992)
S5i/Core/Core Mobile, Volcano Corporation (See FSN 23995)
WASSENBURG WD440, WD440 PT, WD415, WASSENBURG Medical Devices B.V. (See FSN 24011)
Zenith Alpha Spiral-Z Endovascular Leg, William Cook Europe ApS (See FSN 24037)
TomoTherapy Treatment System, Accuray Incorporated (See FSN 24047)
RUSCH Sensor (Series 400) Silicone (179360 & 179361) Rectal Pharyngeal Temperature Sensor, Non-Sterile (1016), Teleflex Malaysia Sdn.Bhd Malaysia (See FSN 24058)
RayStation, RaySearch Laboratories AB (See FSN 24065)
Premicath / Premistar, VYGON GmbH (See FSN 24070)
Fuhrman Pleural/Pneumopericardial Drainage Set, Cook Incorporated (See FSN 24074)
Cook Vital-Port® Vascular Access System, Cook Incorporated (See FSN 24083)
Precise Digital Accelerator, Synergy Platform, Synergy, Synergy S, Infinity, Axesse, Versa HD, Elekta Ltd (See FSN 24092)
SOMATOM Definition AS, Siemens AG (See FSN 24109)
ProtoCERT, F. & M. Lautenschläger GmbH & Co. KG (See FSN 24121)
Hemotherm, Cincinnati Sub-Zero Products (See FSN 24124)
NIM-ECLIPSE® System, MEDTRONIC XOMED Inc (See FSN 24150)
Telemis Medical, Telemis (See FSN 24158)
INFANT/CHILD REDUCED ENERGY ELECTRODES, Physio-Control (See FSN 24165)
IPS CaseDesigner 1.3, Nobel Biocare AB (See FSN 24166)
Vyntus Bodyplethysmograph ; Vyntus Body System including Option Diffusion, Carefusion Germany 234 GmbH (See FSN 24187)
Persona Partial Knee Spacer Blocks, Biomet Orthopaedics Inc. (See FSN 24192)
KYPHON® Express Directional Bone Filler, Medtronic Safamor (See FSN 24199)

Patterson Walking Patterson Walking Frame Wheeled Narrow Medium, Performance Health (See FSN 24202)
Various Hip and Knee products, Zimmer Inc (See FSN 24212)
Signia Power Handle, Covidien llc (See FSN 24252)
ARTIS Systems, Siemens AG (See FSN 24264)
Several, Medline International France SAS (See FSN 24270)
Motiva Implants, ESTABLISHMENT LABS (See FSN 24275)
Carescape R860, Datex-Ohmeda Inc (See FSN 24281)
Guider Softip TM XF Guide Catheter, Boston Scientific Corporation M (See FSN 24284)
Andago V2.0, Hocoma AG (See FSN 24289)
Port & Catheter, Implanted, Subcutaneous, Intravsc, Smiths Medical ASD Inc (See FSN 24338)
SIGMA® HP PFJ Cemented Trochlear Implants., DePuy Orthopaedics (See FSN 24364)

## 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

**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 :*

**01/03/2018 : Salle/Zaal Vivaldi**

à 13h00  
om 13u00