

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

**COMPTE-RENDU DE LA REUNION DU 09 NOVEMBRE 2017
VERSLAG VAN DE VERGADERING VAN 09 NOVEMBER 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	E / V
Maries Merken		Rita Cornélis	
Guibert Crèvecoeur		Jean-Claude Mignolet	
Isabelle De Pau ad it. Tom Clarijs		Annie Vanderlinck	
Guido Van Nooten	P / A (president)	Yves Taeymans	
Hein Heibüchel		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	E / V
Bart Mersseman		Marine Debaut	

Représentants de l'AFMPS - Vertegenwoordigers van het FAGG:

Cedric Vandenbroucke Erina De Thaye	Christophe Driesmans Julie Roothoof Cristina Luchian	Pieter Van De Vijver Ann Jans Vicky Hoymans
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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

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

✓ **Dossier 22877 (CCV):** Trifecta GT valve (St. Jude Medical Costa Rica)

5 Incidents / Incidenten

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

Et / En 55 FSCA:

Integrity, Elekta Ltd (See FSN 13121)
JUPITER / ARTIS / TruSystem 7500, Trumpf Medizin Systeme GmbH (See FSN 16914)
KiWee® Testicular Implant and Vaginal Stent, Coloplast A/S (See FSN 18660)
TruLight 3000, TruLight 5000, iLED 3, iLED 5, TruV, Trumpf Medizin Systeme GmbH (See FSN 19299)
Molift Air 205 & 3000, Etac AS, Etac Supply Gjøvik (See FSN 20447)
EMBLEM S-ICD Programmer, Cardiac Pacemaker Inc. (See FSN 21720)

Medeks(Life-point PRO AED / Life-point bplus / Life point mplus / Medeks), Medeks (See FSN 22151)
DBS Lead Kit for Deep Brain Stimulation, Medtronic Inc. (See FSN 22219)
HeartMate II® System Controller, THORATEC Corp (See FSN 22314)
OVATIO / PARADYM / PARADYM 2 / PARADYM RF / INTENSIA devices, Sorin Group Italia Srl (See FSN 22374)
Tubulure HP Diameter 3mm, Length 150cm Vol1.18ml, PMH - Produtos Medico Hospitalares (See FSN 22416)
Heater-cooler (IT), Heater-cooler 3T, FlexTherm, Sorin Group Deutschland / LivaNova (See FSN 22552)
Werber Countersink Cannulated for micro CBS screws, Zimmer GmbH (See FSN 22715)
Infinity Acute Care System (M540), Draeger Medical System, Inc. (See FSN 22808)
EMBLEM™ S-ICDs, EMBLEM™ MRI S-ICDs and SQ-RX™ S-ICDs, Cardiac Pacemaker Inc. (See FSN 22884)
9733449 Straight Suction EM, ENT; 9733450 Curved Suction 70, EM; 9733451 Short Curved Suction 90, EM; 9734308 Suction Small AxiEM™ ENT, Medtronic Navigation (See FSN 22969)
Pilier calcinable rotationnel « Océan » pour implant / Pilier angulé « Océan » à 15°, Ø4,5mm H=3 mm, SARL EASY SYSTEM IMPLANT (See FSN 23034)
Spinous Process Clamp Tall and Short (Model 9734715 and 9734716), Double Spinous Process Clamp Tall and Short (Model 9734723 and 9734724), Medtronic Navigation (See FSN 23053)
Sensis systems, Siemens AG; Healthcare Sector; Business Unit AX (See FSN 23056)
Aequalis Ascend Flex Shoulder System, TORNIER SAS (See FSN 23078)
Pilier « Océan », SARL EASY SYSTEM IMPLANT (See FSN 23142)
AXS Offset, Stryker Neurovascular-Calif (See FSN 23326)
Infusion Controller/ Infusionsregler STA T2, Accura (See FSN 23345)
Bridge™ Occlusion Balloon, The Spectranetics Corporation (See FSN 23379)
VICRYL RAPIDE™ (Polyglactin 910) SUTURE, Ethicon LLC - Guaynabo (See FSN 23432)
ARTIS, EAZ, LUXIOL, NAVIGO, Cristalens (See FSN 23440)
Allura Xper R9 and Azurion R1.1, Philips Medical Systems Nederland BV (See FSN 23467)
Medtronic MiniMed Infusion Sets only, Unomedical (See FSN 23470)
LENTIS, Oculentis BV (See FSN 23474)

THERMOCOOL® SF NAV, THERMOCOOL SMARTTOUCH® SF Uni-Directional, THERMOCOOL SMARTTOUCH® SF Bi-Directional, THERMOCOOL SMARTTOUCH® Uni-Directional, THERMOCOOL SMARTTOUCH® Bi-Directional, Biosense Webster Inc (See FSN 23476)
Artis, X-Workplace, Sensis and ARCADIS Systems, Siemens AG; Healthcare Sector; Business Unit AX (See FSN 23477)
Prosthesis, internal, joint, knee, tibial component / Tibial Tray, Offset; Offset Spine Stiffener Screw, Exactech Inc. (See FSN 23487)
ACUSON S Family ultrasound systems, Siemens Medical Solution (See FSN 23489)
Emergency Deliver Kit (containing EZ Clamp), Bastos Viegas SA (See FSN 23499)
Artis zee/Artis Q, Siemens AG (See FSN 23501)
expanSys metamys inlay, Mathys AG Bettlach (See FSN 23503)
DELTA XTEND™ Reverse Shoulder System, DePuy France (See FSN 23508)
Delta cup beater-positioner-aligner, Lima - Lto spa (See FSN 23514)
Legion Screw L-Wedge S4 10D x 5P, Smith & Nephew USA (See FSN 23537)
IntelliVue Multi Measurement Server, IntelliVue Multi Measurement Server SLCP, IntelliVue Multi Measurement Server X2, IntelliVue Patient Monitor Models MP2 and MP5, PHILIPS MEDICAL SYSTEMS (DE) (See FSN 23551)
Neuray® Neurosurgical Patties and Strips; Merocel® Neurosurgical Patties and Packing, MEDTRONIC XOMED Inc (See FSN 23566)
Mobile Detector Holder, Philips Medical Systems DMC GmbH (See FSN 23569)
AIRO Mobile CT System, Mobius Imaging, LLC (See FSN 23592)
Brilliance iCT SP Brilliance iCT, Philips Healthcare Ohio (See FSN 23611)
Anaconda™ ONE-LOK™ AAA Stent Graft System / Anaconda™ Iliac Stent Graft System / Anaconda™ AAA Stent Graft System Aortic Cuff, Vascutek Limited (See FSN 23612)
Brilliance BR64, Ingenuity CT, Ingenuity Core, Ingenuity Core128, Philips Healthcare Ohio (See FSN 23613)
AudioSystem- Headphone Slim, NordicNeuroLab AS (See FSN 23624)
Phaseal Secondary Set, C61, Becton Dickinson & Company Limited (See FSN 23627)
Specific Hip and Trauma instruments, Zimmer GmbH (See FSN 23628)
GMK Sphere & GMK Primary PS Inserts - all codes, Medacta International (See FSN 23645)
HYDROSIL Gripper, Personal and Magic3 Intermittent, Rochester Medial Corporation (See FSN 23662)

PUBLIC

DG POST/matériovigilance

PERFUSION TUBING SYSTEMS PHISIO, Sorin Group Italia (See FSN 23668)
Nellix EndoVascular Aneurysm Sealing System, Endologix International Holdings B.V. (See FSN 23669)
Pulsavac Plus, ZIMMER Orthopaedic Surgical Products (See FSN 23684)
AUTO ENDO05 ML / WECK® Auto Endo5® Automatic Hem-o-lok® Clip Appliers, AE05ML, Teleflex Medical (See FSN 23714)

6 Etudes cliniques / Klinische studies

- ✓ 9 klinische studies werden mondeling gepresenteerd tijdens deze Evaluatiecommissie
- ✓ 9 études cliniques ont été présentées oralement durant cette Commission d'Evaluation

7 Varia

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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 :

07/12/2017 : Salle/Zaal Vivaldi

à 13h00
om 13u00