

**PUBLIC**

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

COMPTE-RENDU DE LA REUNION DU 02 MAI 2013  
VERSLAG VAN DE VERGADERING VAN 02 MEI 2013

**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	E/V
Awatif Jebari	P / A	Emmanuelle Gay	E/V
Maries Merken	E / V	Rita Cornélis	
Guibert Crèvecoeur		Jean-Claude Mignolet	
Isabelle De Pau ad it. Tom Clarijs	P/A	Annie Vanderlinck	
Guido Van Nooten	P / A	Yves Taeymans	
Hein Heidebüchel		Rik Willems	
Kristel De Vogelare		Daniel Mojet	P / A
Claude Hanet		André Waleff	
Véronique Kepenne		Johan Somville	E / V
Florence Lefranc		Gaetane Stassijns	
Ludo Willems		Dominique Tøye	
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	P / A

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

Vanackere Sébastien	Eglen Steve	Damien Lambot
Julie Roothoof	Sibylle Watteuw	

Le président ouvre la réunion à 13h15. Le quorum n'est pas atteint.  
*De voorzitter opent de vergadering om 13u15. 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 / Belangenconflicten**

Mr. Mersseman (SGS) a signalé un conflit d'intérêt avec les biberons Beldico vu que SGS est leur Notify Body. Celui-ci a été noté par le secrétariat mais au vu de l'expertise de l'intéressé, il a été demandé qu'il puisse donner son avis sur le sujet sans toutefois participer au vote des actions à mettre en place.

Mr. Mersseman (SGS) heeft een belangenconflict gemeld aangaande Beldico zuigflessen aangezien SGS hun Notified Body is. Hiervan werd nota genomen door het secretariaat, maar gezien zijn deskundigheid werd zijn mening gevraagd over dit onderwerp, zonder inspraak in de uit te voeren acties.

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

1 dossier a été discuté pour suivi / 1 dossier werd besproken ter opvolging

**5 Incidents / Incidenten**

Aucun dossier a été présenté oralement durant cette réunion / Geen enkel dossier werd mondeling gepresenteerd tijdens deze vergadering.

124 FSCA ont été soumis à cette Commission :

- ✓ Somaton Definition AS/AS+ from *Siemens* (see fsn 7270)
- ✓ Contour SE TM Microspheres from *BOSTON Scientific Corporation* (see fsn 7275)
- ✓ Fixation posts from *Elekta* (see fsn 7286)
- ✓ Concerto and Virtuoso from *MEDTRONIC Inc.* (see fsn 7287)
- ✓ Spinnaker Elite TM Flow Directed Microcatheter from *BOSTON SCIENTIFIC CORP* (see fsn 7288)
- ✓ Durom Acetabular Cup from *Zimmer GmbH* (see fsn 7320)

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- ✓ Revolution from *Sorin Group Italia* (see fsn 7326)
- ✓ all Power Medical Intervention products in distribution. all SurgiASSIST R Systems, devices and accessories and all Intelligent Surgical Instruments Systems, devices and accessories from *Power Medical Interventions, Inc* (see fsn 7333)
- ✓ Paradigm Veo insulin pumps from *MEDTRONIC MINIMED* (see fsn 7349)
- ✓ Medena Tapered Tip from *Astra Tech AB* (see fsn 7354)
- ✓ Bryan Cervical Disc System from *Medtronic BV Heerlen* (see fsn 7367)
- ✓ Medtronic BV Heerlen from *KAN MED* (see fsn 7376)
- ✓ Clip-a-Port, EcoPort from *A.M.I* (see fsn 7387)
- ✓ Guider Softip TM XF Guide Catheter from *BOSTON Scientific Corporation* (see fsn 7389)
- ✓ BOSTON Scientific Corporation from *Orto Maquet* (see fsn 7390)
- ✓ Clinac, C Series from *Varian Medical Systems* (see fsn 9163)
- ✓ ETHILON\* Black, ETHILON\* Blue, ETHIBOND\*, MERSILENE, silk from *Johnson & Johnson Medical n.v.* (see fsn 9165)
- ✓ Cholangioscopy Access Balloon/DPOC-15, Cholangioscopy Access Balloon, G54951, 15 mm, Rx only.
- ✓ / DPOC-20, Direct Peroral Cholangioscopy Balloon, G54951, 20 mm/17 mL, Rx Only. from *Cook Endoscopy* (see fsn 9174)
- ✓ System 2450 R from *ConMed Corporation* (see fsn 9177)
- ✓ Ascendra 2(TM)Delivery System from *Edwards Lifesciences* (see fsn 9182)
- ✓ Codman Disposable Drill Kits from *Codman & Shurtleff, Inc.* (see fsn 9190)
- ✓ IAB-05800 Series IAB with SuperArrowFlex (Wire-reinforced) Sheath/ 5800 Series FibreOptix? and Ultra 8 ? Catheters 30 and 40 CC IAB Catheters from *ARROW International* (see fsn 9194)
- ✓ GE Centricity PACS Web Diagnostic Software Versions: 1.0.0.x from *Healthcare Integrated IT Solutions* (see fsn 9195)
- ✓ Intellivue Information Center from *Philips Healthcare* (see fsn 9233)
- ✓ SKYLIGHT Gamma Camera and Precedence Imaging System from *Philips Healthcare Ohio* (see fsn 9234)
- ✓ Xeleris 1.0, Xeleris 1.1, Xeleris 2.0, Xeleris 2.1 and Xeleris 3.0 from *GE Medical Systems Israel* (see fsn 9261)

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- ✓ MHI - TM2000 (vero Linac system 1.0) from *Mitsubishi Heavy Industries* (see fsn 9266)
- ✓ Probes, pulse-co Oximeter, reusable/ Pronto-7 rainbow 4D Reusable Sensor ; Radical from *Masimo* (see fsn 9267)
- ✓ Radiation therapy treatment record/verify system from *Varian Medical Systems (USA)* (see fsn 9273)
- ✓ CADD R Solis Ambulatory Infusion Pump from *SMITHS MEDICAL ASD, Inc* (see fsn 9276)
- ✓ cardioPAT from *Haemonetics Corp USA* (see fsn 9278)
- ✓ Brilliance 6, 10, 16, 16P, 40,64, ICT, ICT SP, Big Bore from *Philips Healthcare Ohio* (see fsn 9280)
- ✓ TomoTherapy R Treatment Systems from *TomoTherapy Incorporated* (see fsn 9286)
- ✓ BeneHeart D6 from *SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD* (see fsn 9287)
- ✓ Desktop Pro from *Elekta Ltd* (see fsn 9299)
- ✓ AXIOM Artis VB23A a VB23H from *Siemens* (see fsn 9300)
- ✓ DERMABOND Topical Skin Adhesive, DERMABOND Mini Topical Skin Adhesive from *ETHICON Inc.* (see fsn 9301)
- ✓ VA34A\_SP2/ Definition + flash from *Siemens* (see fsn 9305)
- ✓ VA34A\_SP2/ Definition + flash from *Siemens* (see fsn 9302)
- ✓ syngo Dynamics from *Siemens* (see fsn 9303)
- ✓ MOBILETT XP from *Siemens Medical Solution* (see fsn 9304)
- ✓ syngo RT Therapist from *Siemens* (see fsn 9305)
- ✓ MOBILETT XP from *Siemens Medical Solution* (see fsn 9307)
- ✓ Nimbus/ Nimbus Paediatric from *Arjo Huntleigh* (see fsn 9308)
- ✓ Fluoroscopic x-ray system, image -intensified from *PHILIPS BEST* (see fsn 9309)
- ✓ VARiS Vision from *Varian Medical Systems* (see fsn 9312)
- ✓ Varian Medical Systems from *Varian Medical Systems* (see fsn 9326)
- ✓ VCARE R Vaginal-Cervical Ahluwalia's Retractor-Elevator from *ConMed Corporation* (see fsn 9332)

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- ✓ Triathlon PKR instruments, peg drill from *Stryker Orthopaedics Mahwah* (no fsn)
- ✓ VS III ventilators from *ResMed Ltd* (see fsn 9351)
- ✓ ARIA from *Varian Medical Systems* (see fsn 9360)
- ✓ Fraxel re:store R Dual Laser System from *Solta Medical, Inc* (see fsn 9369)
- ✓ Lucas 2 from *Gambro Lundia AB* (see fsn 9373)
- ✓ PlivioPore/ PlivioPore, Osteoconductive Titan Structure from *Synthes GmbH* (see fsn 9385)
- ✓ Level 1 Normothermic I.V. Fluid Administration Sets from *SMITH MEDICAL ASD, Inc* (see fsn 9387)
- ✓ HeartAttendant from *Micromed Cardiovascular, Inc.* (see fsn 9391)
- ✓ Alcon Custom Pak/ Microlance 30G x 1/2 Needles included in Select Modles of alcon Customs Paks from *Alcon Laboratories* (see fsn 9392)
- ✓ NX - Image acquisition and processing station from *AGFA GEVAERT NV* (see fsn 9393)
- ✓ Tige femorale de reconstruction EXTREME from *Amplitude* (see fsn 9395)
- ✓ Green Light IITM Laryngoscope Handle, Green Light IITM Battery Cartridge (see fsn 9406)
- ✓ Reporting Tool from *GE Medical Systems* (see fsn 9408)
- ✓ EndoVims; VSX10030HD/ 30 Coverable endoscopic camera - Camera endoscopique gainable 30 from *VIMS* (see fsn 9423)
- ✓ Air Bubble Detector Module and Occluder Module from *Terumo Cardiovascular Systems* (see fsn 9425)
- ✓ Monoaxial screws ODALYS from *Kisco International* (ssee fsn 9426)
- ✓ Carescape B 850 from *GE Medical Systems Information Technologies* (see fsn 9467)
- ✓ IntelliVue Clinical Information Portfolio (ICIP) from *Philips Healthcare* (see fsn 9507)
- ✓ Cory Bros Part Codes, Purple Surgical Part Codes from *Cory Bros Ltd* (see fsn 9518)
- ✓ Terumo Myocardial Protection Sets: Cardioplegia Table Line Connector from *Terumo Medical Corporation* (see fsn 9523)

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- ✓ Adapta, versa, EnPulse, Kappa 600, 700, 800, 900, Relia and Vitatron from Medtronic Inc. (see fsn 9541)
- ✓ Kalix II Sterile from Newdeal SAS (see fsn 9546)
- ✓ MX 16-slice from Philips and Neusoft Medical Systems Co., Ltd (see fsn 9550)
- ✓ GMD Universal Female Urinary Incontinence Sling from Generic Medical Devices, Inc. (see fsn 9557)
- ✓ Brilliance 64, Brilliance Big Bore, Brilliance Ict, Brilliance Ict SP, Ingenuity CT from Philips Healthcare Ohio (see fsn 9559)
- ✓ Brilliance 64, Brilliance Big Bore, Brilliance Ict, Brilliance Ict SP, Ingenuity CT from Philips Healthcare Ohio (see fsn 9560)
- ✓ Therakos UVAR CTS Photopheresis System from Therakos (see fsn 9561)
- ✓ Beamview from Siemens (no fsn)
- ✓ Syngo RT Therapist from Siemens (see fsn 9567)
- ✓ AXIOM Artis, Artis Zee, Artis Zeego from Siemens (see fsn 9569)
- ✓ H14, H18, H27, H29, HCX from Varian Medical Systems (see fsn 9586)
- ✓ TEMPOFILTER II (see fsn 9595)
- ✓ S8-3t Micro TEE Transducer from Philips Health Care (see fsn 9598)
- ✓ Omniflush from B. BRAUN MEDICAL n.v. (see fsn 9603)
- ✓ Ultraview SL from Spacelabs Medical (see fsn 9613)
- ✓ Clinac from Varian Medical Systems (see fsn 9622)
- ✓ X-ray remote controlled table from Stephanix (see fsn 9623)
- ✓ Portable Bedside Capnograph/Pulse Oximeter from Tyco Healthcare (see fsn 9626)
- ✓ Cortoss Delivery Gun from ORTHOVITA Inc. (see fsn 9647)
- ✓ Avenir Mueller Stem from Zimmer (see fsn 9653)
- ✓ 2.24 programmer software version from Eros RONCAIA-SORIN BIOMEDICA CARDIO (see fsn 9662)
- ✓ Carescape B850 from Ge Healthcare Finland (see fsn 9663)
- ✓ Paradym from Eros RONCAIA-SORIN BIOMEDICA CARDIO (see fsn 9664)
- ✓ Carescape B650 from Ge Healthcare (see fsn 9665)
- ✓ Optical Guidance Platform (OGP) from Varian Medical Systems (see fsn 9669)

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- ✓ ARTISTE MV, 8139789 from *Siemens* (see fsn 9673)
- ✓ Optima MR450w, Discovery MR450, Discovery MR750, Signa HDx. Signa HDxt, Signa HFO, GE 1.5T Signa
- ✓ HDe, GE 1.5T Signa HDsv, Signa Excite 1.5T & 3T from *Ge Medical Systems* (see fsn 9682)
- ✓ Infusable Pressure Infusor, InfusaScan™ Pressure Infusor from *Vital Signs Devices* (see fsn 9695)
- ✓ Mammomat Inspiration from *Siemens* (see fsn 9711)
- ✓ Syngo Imaging from *Siemens* (no fsn)
- ✓ ACUSON & SONOVISTA X300 from *Siemens Medical Solution* (no fsn)
- ✓ Nikkiso blood tubing set for haemodialysis from *Nikkiso Co. Ltd* (see fsn 9718)
- ✓ FLOW-I from *Maquet* (no fsn)
- ✓ 7F SafeSheath Tearaway Kit 13cm, 9F SafeSheath Tearaway Kit 13cm, Transvalvular Insertion Tool Kit
- ✓ SafeSheath Sealing Adapter Kit, SafeSheath Sealing Adapter Kit with Wing Extension Kit from *ORTHOVITA Inc.* (see fsn 9728)
- ✓ LogiCal Pressure Monitoring System; TranStar Pressure Monitoring System ; and NovaTrans Pressure Monitoring System from *Smiths Medical International, Ltd* (see fsn 9753)
- ✓ MS2 Mobile Stand (used with the MoorLD12 Laser Doppler Imager) from *Moor Instruments Ltd* (see fsn 9787)
- ✓ High/low Lifting bath electromechanic height adj. from *Meditechnik DE* (see fsn 10866)
- ✓ Gymna Couches from *GYMNA UNIPHY* (see fsn 11072)
- ✓ Single Use Laryngoscope / RUSCH Macintosh Laryngoscope Disp.Metallic Kit from *M.A. ARAIN & BROTHERS (PVT) L TD.* (see fsn 11316)
- ✓ Damon 3MX Bicuspid Brackets from *Ormco Corporation* (see fsn 11516)
- ✓ Angled Surecan from *B. Braun Medical Inc.* (see fsn 11959)
- ✓ Drill Bit 2.5mm, L 220mm, 2-flute and Fixation Sleeve for Vectra System from *Synthes GmbH* (see fsn 11964)
- ✓ IMPAX CV DICOMstore with Media Purge Daemon from *Agfa HealthCare N.V.* (see fsn 11985)

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- ✓ INTERLINK System BURETROL Solution Set with 150mL Burette (Ball-Valve Drip Chamber) from *Baxter Healthcare Corporation* (no fsn)
- ✓ A.T.S. 3000 Tourniquet System from *Zimmer, Inc.* (see fsn 12057)
- ✓ Tonometer Measuring Prisms from *Haag-Streit AG* (see fsn 12106)
- ✓ CT-compatible Intubation Head Ring Assembly from *Integra Burlington* (see fsn 12236)
- ✓ Seno Advantage 2.1 and Seno Advantage 2.2 from *GE Medical Systems* (see fsn 12240)
- ✓ (1 )Visum Halogen Surgical Light, (2) Visum LED Surgical Light, (3) Stryker Flat Panel & Navigation Arm from *Stryker Communications* (see fsn 12245)
- ✓ REA Azalea Base from *Invacare Rea AB* (see fsn 12376)
- ✓ Swift Mobil from *Etac Supply Center AB* (see fsn 12438)
- ✓ Quadra Trial Broach size 0 from *Medacta International* (see fsn 12505)
- ✓ RUSCH Macintosh Laryngoscope Disp.Metallic Kit from *M.A. ARAIN & BROTHERS (PVT) L TD.* (see fsn 12555)
- ✓ syngo Workflow MLR from *Siemens AG* (see fsn 12645)
- ✓ Triathlon Baseplate Impactor Extractor from *Stryker Orthopaedics Mahwah* (see fsn 12883)
- ✓ Philips IntelliVue Information Center iX from *Philips Medical systems* (see fsn 12924)

## 6 Etudes cliniques / Klinische studies

10 études ont été présentées / 10 studies werden gepresenteerd.

## 7 Varia :

### • Oxyconcentrateur / Zuurstofconcentrator

Suite au point varia de la réunion précédente, nous avons reçu et présenté 2 documents reprenant des directives sur l'usage par des 'non-professionnel' de ces produits.

*Ingevolge het punt varia van vorige vergadering, hebben wij 2 documenten, met richtlijnen voor het gebruik door 'niet-professionelen' van deze producten, ontvangen en gepresenteerd.*

### • Les sessions de la Commission de juillet et août 2013 / De zittingen van de Commissie in juli en augustus 2013



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Les réunions de la Commission d'Evaluation de juillet et août sont annulées.

*De Evaluatiecommissie van juli en augustus geannuleerd zijn.*

- **Simethicone**

SGS a été contacté pour être le Notify Body (NB) d'un produit qui sera vendu en Belgique dont le principe actif est du Simethicone. Un produit similaire est déjà sur le marché belge en tant que DM sous le nom d'Infacol et dont le NB est Medcert (Allemagne). produit présente certaines caractéristiques d'un médicament.

La Commission d'Evaluation conseille à SGS de demander l'avis à la commission mixte sur le statut de ce produit (médicament ou produit médical).

*SGS werd gecontacteerd met de vraag om als Notified Body op te treden voor een product, met als actief bestanddeel Simethicon, dat in België zal worden verkocht. Een gelijkaardig product is al op de Belgische markt als medisch hulpmiddel onder de naam Infacol. De NB voor dit product is Medcert (Duitsland).*

*Dit product vertoont enkele kenmerken van een geneesmiddel.*

*De Evaluatiecommissie adviseert SGS om inzake het statuut van dit product (hetzij geneesmiddel, hetzij medisch hulpmiddel) het advies van de Kamer voor producten voor menselijk gebruik van de Gemengde Commissie in te winnen.*

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 :*

**06/06/2013 : Salle/Zaal 06D285**

à 13h  
om 13u