

# Bijeenkomst Ontwikkeling in medische hulpmiddelen regelgeving

**Amersfoort, 31 maart 2010**

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# BSI Profile



## Medical Device Notified Body serving the Globe

- hubs in London, Washington DC, Frankfurt, Tokyo
- Designated in UK (MHRA) and Germany (ZLG)

## Broad Reach, Sharp Focus

- Full product scope including drug-device combinations
- Serving > 85% of top 50 Multinationals
- Focus on innovative start-ups
- Class III devices – reliable fast-track programs

## Market Access across the Globe

- Japan: J-PAL
- USA: 510(k), FDA inspections
- Canada: CMDCAS
- Australia
- Taiwan, Hong Kong
- Singapore

## Globally operating teams of experts

- orthopedic & dental devices & Implants
- Vascular devices & Implants
- Active implantables (AIMD)
- Active medical devices (electro-medical)
- Non-active devices (wound care, Ophthalmics, drug-device combinations, animal tissue)

## Specialist Support expertise

- Software    Clinical evaluation    Animal Tissues
- Microbiology    Biocompatibility    Human Blood Derivatives

## Praktische zaken

- Nooduitgangen



- Mobiele telefoons

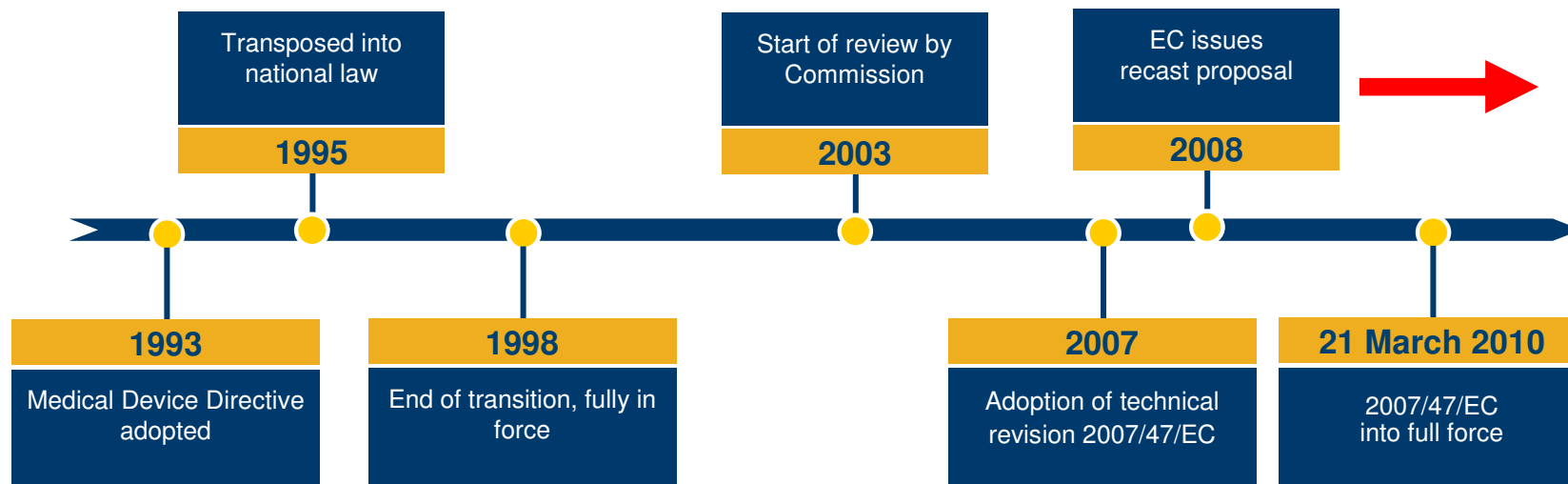


- Evaluatie formulier
- Presentaties: [www.bsigroup.nl](http://www.bsigroup.nl)

# History

- “The Commission shall, no later than 5 years from the date of implementation.....submit a report .....and if necessary make appropriate proposals

## *93/42/EC Article 11.4*



## Ontwikkelingen in medische hulpmiddelen regelgeving

|       |  |                    |
|-------|--|--------------------|
| 14:00 | Opening  | Dhr. J. van Lochem |
| 14:10 | Herziene Richtlijn 2007/47/EC: het venijn zit in de staart   | Dhr. J. Kraus      |
| 14:30 | Herziene Richtlijn 2007/47/EC: eerste praktijk ervaring en implementatie MEDDEV 2.7.1: klinische evaluatie | Dhr. G. Bos        |
| 15:00 | Toekomstvisie regulering Medische Hulpmiddelen: "I have a dream ...."                                      | Mevr. S. Hoekstra  |
| 15:30 | Pauze  |                    |
| 16:00 | Reimbursement – the new hurdle for medical device companies  | Dhr. M. Kyhlstedt  |
| 16:30 | Panel discussie  |                    |
| 17:15 | Slotwoord  | Dhr. H. Hurts      |
| 17:30 | Receptie   |                    |
| 18:30 | Einde  |                    |

# Evaluatie formulier

ewertung

Sehr gut

Gut

Befriedigend

Ausreichend

Mangelhaft





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