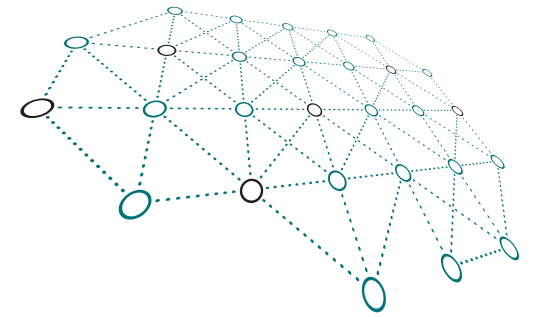


# 4S Leverandørforum



## Understøttelse af CE-mærkning – et centralt element i en flerleverandørstrategi

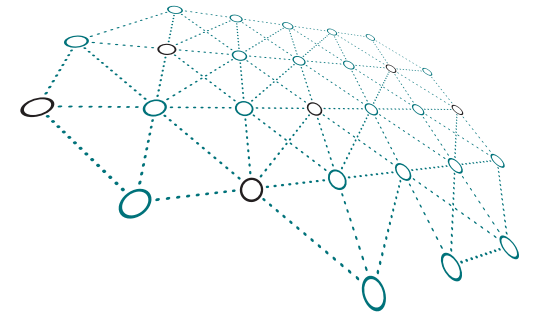
Morten Kyng, koordinator 4S

10. december 2015



STIFTELSEN FOR SOFTWAREBASEREDE SUNDHEDSSERVICES

# 4S



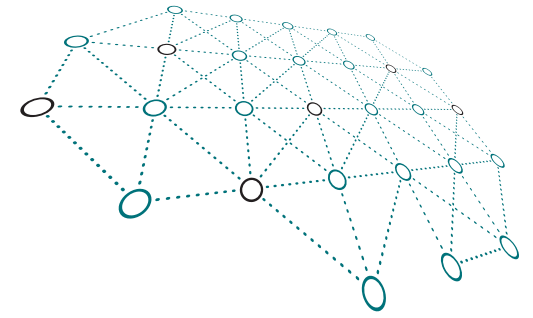
- En fællesoffentlig organisation der har governance

og eksplicit understøtter

- En flerleverandør-strategi med
- plads til SMVer og innovation



# En flerleverandør-strategi

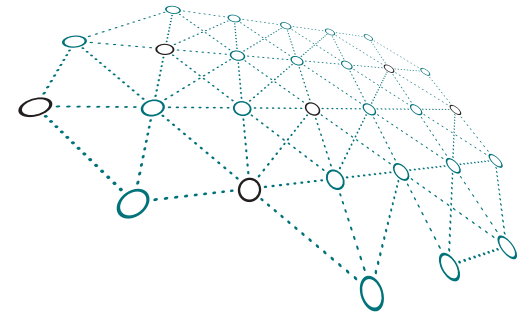


Forskellige firmaer

- Laver moduler
- Leverer løsninger til kunder

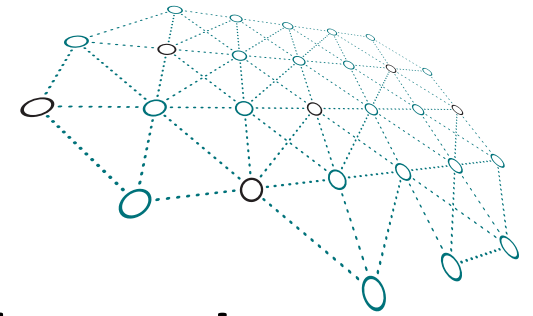


# CE mærkning



- Produkter CE-mærkes
- Den der mærker har ansvar

# CE mærkning & MDD



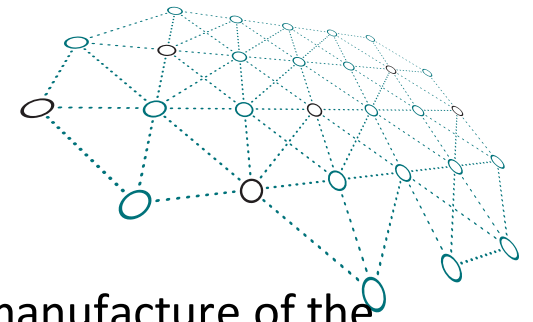
CE-mærkning vil, hvor relevant, betyde at Medical Device Directive er overholdt

Medical Device Directive stiller krav til

- Processer hos den der mærker
- Softwareudviklingsprocesser
- Dokumentation



# Classification in MDD

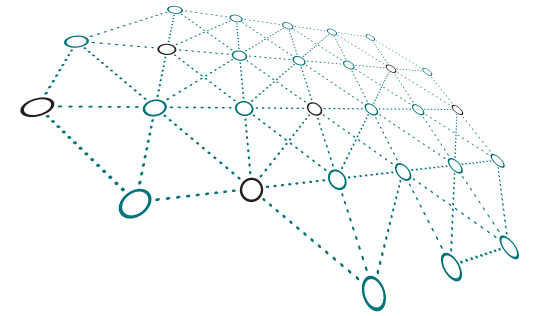


- Four product classes based on risks associated with design and manufacture of the device
  - Class I:  
conformity assessment procedures can be carried out under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products
  - Class IIa:  
the intervention of a notified body should be compulsory at the production stage
  - Class IIb (and III):  
devices constitute a high risk potential, inspection by a notified body is required with regard to the design and manufacture of the device
  - Class III:  
the most critical devices for which explicit prior authorization with regard to conformity is required for them to be placed on the market.

Ref: 93/42/EEC-2007/47/EC Medical Device Directive



# CE-mærkning af SW



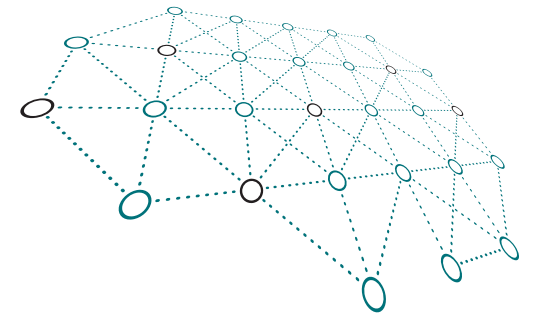
Standard 62304:

sw udviklingsprocesser for medicinsk udstyr

- Safety classes for software:
  - Class A: No injury or damage to health is possible
  - Class B: Non-SERIOUS INJURY is possible
  - Class C: Death or SERIOUS INJURY is possible



# CE mærkning



## 4S vil understøtte

- Processer a la "hos den der mærker"
  - Softwareudviklingsprocesser
  - Dokumentation
- 
- For at reducere indsats for mærkning

