



Rijksinstituut voor Volksgezondheid
en Milieu

*Ministerie van Volksgezondheid,
Welzijn en Sport*

RIVM onderzoek classificatie IVDs

Arjan van Drongelen

15 juni 2018



Rijksinstituut voor Volksgezondheid
en Milieu

*Ministerie van Volksgezondheid,
Welzijn en Sport*

Inhoud

1. Introductie RIVM
2. Classificatie IVDs
 1. IVDD
 2. IVDR
3. RIVM onderzoek



Introductie RIVM

- Missie:
Het RIVM beschermt en bevordert de gezondheid van de bevolking en de kwaliteit van het leefmilieu.
- Opdrachtgevers:
 - Ministeries
 - Inspecties
 - Internationale organisaties
- Centrum voor Gezondheidsbescherming
- Medische technologie
 - IGJ
 - Ministerie VWS, directie GMT





RIVM en IVDs

Veel raakvlakken met IVDs:

- Regie bevolkingsonderzoeken
- Screening zwangeren en pasgeborenen
- Advies en onderzoek
 - In-house testing
 - IVDs voor zelftesten
 - Personalized medicine



Classificatie IVDs, IVDD

Risicogestuurde markttoelating

- Weinig risico: zelfcertificatie
- Hoe hoger risicoklasse, hoe 'zwaarder' de toelatingsprocedure
 - Inzet zgn notified bodies
- Eisen aan IVD niet lager!

IVDD:

- Lijst A: hoogste klasse
- Lijst B: midden klasse
- Zelftest: speciale klasse (alleen aspect zelf testen beoordeeld)
- Geen lijst: laagste klasse, zelfcertificatie, geen notified body



Classificatie IVDs, IVDD

- **List A**

- determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell
- markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D

- **List B**

- determining the following blood groups: anti-Duffy and anti-Kidd,
- Determining irregular anti-erythrocytic antibodies
- congenital infections: rubella, toxoplasmosis
- hereditary disease: phenylketonuria
- human infections: cytomegalovirus, chlamydia
- HLA tissue groups: DR, A, B
- tumoral marker: PSA
- trisomy 21
- self-diagnosis of blood sugar



Classificatie IVDs, IVDR

IVDR:

- Geen lijsten meer
- 4 risicoklassen (A-D, laag-hoog)
- Algemene classificatieregels
- Systematiek gelijk aan 'gewone' medische hulpmiddelen

7 regels

- Regel 1, klasse D
 - Transmissible agent in blood, blood components, cells, tissues or organs for transfusion, transplantation or cell administration;
 - ...transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation;
 - ..infectious load of a life-threatening disease where monitoring is critical in the process of patient management.



Classificatie IVDs, IVDR

- Rule 2
 - Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration, are classified as **class C**,
 - except when intended to determine any of the following markers: ABO system ..., Rhesus system ..., Kell system, Kidd system, Duffy system ..., in which case they are classified **as class D**.



Classificatie IVDs, IVDR

- Rule 3 (class C)
- .. a sexually transmitted agent;
- ... an infectious agent in cerebrospinal fluid or blood without a high or suspected high risk of propagation
- ... an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to ..
- pre-natal screening of women in order to determine their immune status towards transmissible agents
- infective disease status or immune status, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for ..
- a companion diagnostic
-disease staging, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation....



Classificatie IVDs, IVDR

- .. screening, diagnosis, or staging of cancer
- human genetic testing;
- ... medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation
- for management of patients suffering from a life-threatening disease or condition
- screening for congenital disorders in the embryo or foetus
- screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.



Classificatie IVDs, IVDR

Rule 4

- Devices intended for self-testing are classified as **class C**, except for devices for the detection of pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, *erythrocytes*, *leucocytes* and bacteria in urine, which are classified as **class B**.
- Devices intended for near-patient testing are classified in their own right.

Rule 5 Class A

- products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains...
- instruments intended .. specifically to be used for *IVD* procedures
- specimen receptacles



Rule 6 (**Class B**)

- Devices not covered by the above-mentioned classification rules are classified as class B.

Rule 7 (**Class B**)

- Devices which are controls without a quantitative or qualitative assigned value are classified as class B.

Application rules

- hoe regels toe te passen, bijv.
 - wanneer meerdere regels van toepassing, neem de hoogste
 - hoe om te gaan met software



RIVM-onderzoek classificatie IVDs

- Nieuwe classificatieregels: meer IVDs naar NB
- Minder IVDs vallen onder direct toezicht van IGJ
- IGJ wil daarom inzicht in verschuiving (80-20?!)
- Vraag aan RIVM: geef indicatie verschuiving IVDs die niet naar NB hoeven bij overgang naar nieuw classificatiesysteem uit IVDR

Uitvoering

- Gebruik database notificaties IVDs bij CIBG (ca. 5500)
- In lijst huidige classificatie (Lijst A, Lijst B, zelftest, 'gewone' IVD)
- Toepassing classificatieregels op entries
 - Indicatie verschuiving oude naar nieuwe classificatie
- Selectie uit database (statistische analyse)



RIVM-onderzoek classificatie IVDs

Resultaten

- Inzicht in impact nieuwe classificatieregels, m.n. voor betrokkenheid NB
- Inzicht in aandachtspunten bij toepassing van classificatieregels

- Onderzoek nog niet afgerond, publicatie in Q4 2018



RIVM-onderzoek classificatie IVDs

Wat zijn jullie ervaringen met de classificatieregels?

