DUTCH PENALTY CLAUSES UNDER MDR with an example May, 2021

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Purpose of the document:

Ensure that under the MDR 2017/745 per the 26th of May, 2021, there is governing law that allows the Dutch government to issue measures in response to breaches against violations of the law mentioned. The document is an appendix to the implementation of the Wet Medische Hulpmiddelen in the Netherlands (2342978-1006451-WJZ). It provides the Dutch government with the possibility to issue measures for each separate violation.

The appendix transposes the applicability of the measures from the MDD 93/42/EEC to the MDR 2017/745.

Formally, the Dutch government can issue the following type of measures: **1)** written warning letter, **2)** a direct penalty, **3)** written warning letter or a direct penalty, an order for incremental penalty payments or special measures. If an order for incremental penalty payments or special measures were imposed (under 3), the government can issue for that same offence immediate penalties.

To determine how measures are defined, the following steps are followed:

Step 1: Determine the severity of the breached clause

Former penalty overview (MDD 93/42/EEC):

Legal basis for measures (article)	Clauses under which penalties can be issued	Severity level	Normative Amount	Type of measure
14.1.c	3, 5, 9a	***	€ 150.000	3
14.1.c	6	***	€ 150.000	2
14.2.c	4, 5a, 5b	*	€ 75.000	3

Correspondence between MDD 93/42/EEC and new MDR 2017/745:

Clause under MDD	Clause under MDR	Severity level	Normative Amount	Type of measure
14.1.a	5.1, 5.3, 6.1, 6.2, 6.4, 7, 9.3, 9.4, 10.1, 10.2, 10.3, 10.4, 10.5, 10.9, 10.10, 10.12, 10.13, 10.14, 13.1, 13.5, 13.6, 13.7, 13.8, 13.10, 14.1, 14.3, 14.4, 14.5, 14.6, 17.1, 17.6, 17.7, 18.1, 22.3, 23.1, 25.2, 27.3, 27.5, 27.9, 52.1, 52.2, 52.3, 52.4, 52.6, 52.7, 52.8, 52.9, 52.10, 52.11, 58.1, 83.1, 83.2, 83.3, 83.4, 84, 85, 86.1, 87.1, 87.11 (second and third sentences), 87.3, 87.4, 87.5, 87.8, 88.1, 89.1, 89.8, 94, 95.3	***	€ 150.000	3
14.1.a	5.2, 5.5, 10.6, 10.7, 10.11, 11.1, 11.3, 13.2, 14.2, 16.3, 16.4, 17.8, 19.1, 19.2, 20.1, 20.3, 20.4, 21.2, 22.5, 27.4, 27.7, 27.8, 29.1, 29.2, 31.1, 31.4, 86.2 (first sentence), 86.3, 87.6, 87.7, 88.2, 89.5	**	€ 150.000	3

14.2.a	6.3, 10.8, 10.15, 10.16 (second paragraph), 11.6, 12, 13.3, 13.4, 13.9, 15, 20.2, 20.5, 20.6, 21.1, 22.1, 22.2, 27.6, 29.3, 29.4, 30.3, 32.1, 32.2, 37.3, 37.5, 46.5, 53.2, 53.3, 54.3, 55.1, 56.1, 56.5	*	€ 75.000	3

Step 2. The nature of the product

The classification of the medical device, either as a medical device or IVD impacts the normative amount to be issued per schedule A below.

Schedule A

Nature of the product	% of the normative amount
Class I / Low-risk IVD	33%
Class IIa / IIb / Medium-risk IVD	66%
Class III / High-risk IVD	100%

Step 3. Determine the severity of the violation

There are a number of defined criteria to help determine whether there are mitigating or aggravating conditions applicable to the violation, the table below provides more details.

Schedule B

	Scale	Impact	Examples
Size of the violation	small	Mitigating	Bulk produce class I: small: qty 100, large: qty 500 Low produce class II or III: small: qty 5, large: > 10
	medium	none	
	large	Aggravating	
Duration of the violation	short	Mitigating	Short: < month Long: > year
	medium	none	
	long	Aggravating	
Reach of the violation	small	Mitigating	Custom-made: small European distribution: large
	medium	none	

	large	Aggravating	

Step 4: Determination of the preliminary measure

The outcome based on steps 2 and 3 are calculated and consequently the following considerations should be made: A) there are one or more mitigating circumstances, B) there are no mitigating circumstances, or aggravating circumstances C) there are aggravating circumstances.

Schedule C

Circumstances	The below impacts the measure in **Schedule A**		
	*	**	***
A)	20%	50%	80%
B)	30%	60%	90%
C)	40%	70%	100%

Step 5. Culpability

An assessment is made on whether the violator has undertaken actions to prevent the violation before it was established. If there is a reduced level of culpability, e.g. the violator has tried its best efforts to prevent the violation, the penalty might be reduced by a maximum of 30% based on **Schedule D** (which indicates that the reduction is either 0% or 30%).

Step 6. identity of the violator

It is further determined whether the violator is a natural person, a natural person in charge of an organisation or a legal person driving an organisation. The size of the organisation, based on the total number of FTE, further determines the impact of the penalty. If a natural person or company size up to 4FTE the penalty shall entail 10% of what was established in Schedule D. For organisations larger than 151 FTE and more, a total of 100% of the penalty determined under Schedule D applies. (there are additional intermediary steps in terms of size of organisation, refer to Schedule E).

Step 7. Repeated violation

If within a period of 4 years after a previous penalty was issued, a new penalty is issued under the same clause, the total amount established under step 6 will be doubled.

What does this mean regarding the requirements for a 'Person Responsible for Regulatory Compliance'?

Example 1. A company fails to appoint a PRRC

This is considered a violation of clause 15 under the MDR, and thus is considered to be of low severity with a normative amount of €75.000,-.

For a large manufacturer (e.g. 200 FTE), which produces large volume (500+) class III products throughout the European Union without having taken actions to prevent the violation (severe violation) for a long period of time (over a year), they would be eligible for a penalty of €75.000,-.