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WELMEC

Informative Document

Screening project for market surveillance of non-automatic weighing instruments for medical use

Prepared by
Working Group 5 Metrological Supervision

July 2020

WELMEC

European Cooperation in Legal Metrology

Medical Weighing Market Surveillance Screening Project

Working Group 5

Final Project Report

July 2020

Contents

1 Project Description

A Market Surveillance project on non-automatic weighing instruments (NAWI) used for medical weighing to determine compliance with the requirements of 2009/23/EU or 2014/31/EU (NAWI Directive).

This project was a combination of market surveillance and inspection in use. The objective of this operation was to verify that medical weighing instruments fulfil the specific regulation at a European level (market surveillance).

The study was intended to broaden the knowledge base of the risks of non-automatic weighing instruments used for patient weighing in the European Union.

2 Project Background

Patients are weighed to calculate medication dosage, diagnose illness, monitor treatment and assess nutritional status. The use of inaccurate or unsuitable patient weighing equipment could be detrimental to patient care. For example, the most serious is an error in accuracy on scales used in the department of nuclear science, which is responsible for calculating chemotherapy dosages for cancer patients. Other problems could include the use of uncontrolled / non-compliant equipment, including weighing scales purchased from high street chemists or domestic kitchen scales being used in maternity or postnatal intensive care units.

Anecdotal evidence, and work done by other Market Surveillance bodies, would suggest there may be problems with the equipment used in medical environments like hospitals and medical centres. The UK has found non-compliance rates of 23% for this instrument type while Belgium has found non-compliant rates of 25% for this instrument type. The consequences of non-compliance of these instruments could have devastating effects on patient care and safety.

This project, under WELMEC Working Group 5 explored these issues with the aim of helping the medical sector to improve their standards by raising the importance of weighing equipment in a medical environment.

Directive 2014/31/EU, the NAWI-directive relating to the making available on the market of non-automatic weighing instruments applies to all non-automatic weighing instruments, but only when used or intended to be used for the applications listed in points (a) to (g) of Article 1. In these cases, they shall satisfy the essential requirements set out in Annex I of the NAWI-directive.

3 Joint Action

The findings by the UK and Belgium authorities in 2017 convinced the market surveillance authorities from WELMEC Working Group 5 to agree to this joint action proposal. This joint action will be the first joint action taken in Europe in the field of market surveillance of medical weighing NAWI and will help market surveillance authorities to pool resources and expertise. The limited effort required per Member State makes it possible that many members participate in the action.

4 Project Justification

- Make the medical sector aware of the requirements of the 2014/31/EU
- The interpretation of the Directive about how to handle the conformity assessment procedure is not uniform. In the medical sector, the requirement of the NAWI directive is not very clear in spite of point (d) from article 1 of 2014/31/EU: (d) Determina-

tion of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment".
- Lack of expertise about this kind of equipment in some EU countries so they don't do market surveillance in this particular field of the NAWI directive.
- Lots of non-conformities found, for example the marking required by directive is missing.
- UK found 23% non-compliance and Belgium 25% non-compliance of NAWIs for medical use. This high number can have the consequence of incorrect measurement and this can affect health.

5 Project Objectives/Deliverables

- To assess current standards of weighing instruments in hospitals, medical centres, homes for the elderly, medical institutions and health care centres
- To determine the compliance of non-automatic weighing instruments used for medical weighing
- To raise the profile of legal metrology
- To make users of medical weighing instruments aware of the legal requirements i.e. 2014/31/EU.

6 Project Participants

The following countries participated in this project:

Country	Contact Name	Contact E-mail
Ireland	Paul Turner	paul.turner@nsai.ie
Germany	Detlef Hoffmann	detlef.hoffmann@lbme.nrw.de
Norway	Martin Vandbakk	mva@justervesenet.no
United Kingdom	Christine Munteanu	christine.munteanu@beis.gov.uk
Netherlands	Hermine van Rij	hermine.vrij@agentschaptelecom.nl
Slovenia	Dušanka Skrbic	dusanka.skrbic@gov.si
Slovakia	Anna Vrábelová	anna.vrabelova@smi.sk
Iceland	Bjarni Bentsson	bjarni@neytendastofa.is
Greece	Filippos Matsoukis	fmatsoukis@gge.gr
Italy	Giovanni De Sanctis	giovanni.desanctis@mise.gov.it

Figure 1. Project Participants

7 Relevant Legislation

7.1 Regulations

The Directive 2014/31/EU on non-automatic weighing instruments, preliminary observation requires compliance with the essential requirements.
Regulation (EC) No 765/2008 of the European Parliament and the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

7.2 Harmonized Standards

EN 45501: 2015 Metrological aspects of non-automatic weighing instruments.

7.3 Guides

WELMEC Guide 5.2 – Market Surveillance Guide (NAWI & MID)
WELMEC Guide 5.3 – Risk Assessment Guide for Market Surveillance: Weigh and Measuring Instruments
The "Blue Guide" on the implementation of EU product rules 2016

8 Instrument Types and Location

This project focused on class III and IV:

- Bed weighers and chair weighers used in oncology centers
- Baby weighers used in pediatrics

This project did not cover weighing instruments used for pharmaceutical use.

A minimum of 20 different type of NAWI were inspected by each Member State. These NAWI's were placed onto the market within the last 10 years.

Inspections took place at locations where medical weighing NAWI's where in use for their stated purpose, i.e. hospitals, medical centers. All relevant hospital procedures in relation to good hygiene practices were followed.

Before the visit took place, the inspecting officer contacted the relevant person in the medical facility with responsibility for the patient weighing equipment. They agreed in advance a date and time for the inspection to take place.

9 Visual Inspection and Metrological Testing

The surveillance included a visual inspection and a metrological test to determine the accuracy of the instrument as per elements of EN 45501. Before commencing the visual inspection and metrological test the following information was recorded:

- Instrument manufacturer
- Instrument Type
- Instrument Model
- Instrument Serial Number
- Min & Max Capacity
- Verification Scale Interval e
- Scale interval d
- Accuracy Class
- Units of Measurement
- Analogue or Digital
- Software Version (if applicable)
- Instrument Class Specification, see table 1

Class	Verification scale interval (e)	Number of verification scale intervals n = Max/e		Minimum capacity (Min)
		Minimum	Maximum	
I	0.001 g ≤ e	50 000	-	100e
II	0.001 g ≤ e ≤ 0.05g 0.1 g ≤ e	100 5 000	100 000 100 000	20e 50e
III	0.1 g ≤ e ≤ 2 g 5 g ≤ e	100 500	10 000 10 000	20e 20e
IIII	5 g ≤ e	100	1000	10e

Source: NAWI Directive – 2014/31/EU

Table 1: The Specification of the Accuracy Classes of the Instrument

9.1 Visual Inspection

The following NAWI visual inspection was carried out, before conducting the metrological test:

9.1.1 Instrument Setup

- The instrument is affixed to/sitting on a suitably stable platform that does not promote movement. ***Record Pass / Fail***
- The instruments pan/platform is level and there are no obstructions to the instruments operation. ***Record Pass / Fail***
- The instrument is in a clean and serviceable condition**. *Record Pass / Fail***
- Is the NAWI included in a quality system? **Yes / No** If yes, indicate calibration interval.

9.1.2 Conformity to type

- Determine if the instrument has a valid type examination certificate. ***Record Pass / Fail***
- Determine if the instrument has a valid declaration of conformity. ***Record Pass / Fail***

**** For information, all TAC and TC are available on the paying database Emetas (European Metrology Type Approvals Service).***

9.1.3 Data Plate

- *Ensure that the NAWI has a data plate with the legally relevant information.* ***Record Pass / Fail***

9.1.4 Marks

- Ensure that the instrument bears the correct CE and Metrological markings as per 2014/31/EU or 2009/23/EU ***Record Pass / Fail***
- Ensure that the instrument bears a Notified Body number. ***Record Pass / Fail***

9.1.5 Security, marks and seals

- Security mark(s)/seal(s) in place and show no signs of tampering. ***Record Pass / Fail***
- Mark(s)/Seal(s) are applied correctly, as per the instruments type approval document. ***Record Pass / Fail***

9.2 Metrological Inspection

This test was carried out with determination of the error using the method described in Standard NF EN 45501. The metrological results were compared with the maximum permissible error in service, see table 2.

The standard weights or standard masses used for inspection of the instrument shall conform to the metrological requirements of OIML R111 and the correct class of weight should be used in relation to the instrument class.

9.2.1 Repeatability

Apply approximately 50% of maximum load. Five weighing's on classes III and IV.

Analogue and Digital Indicating Instruments

i. Zero the instrument's indicator.
ii. Apply test load and record indication
iii. Remove the test load.
iv. Zero the instrument indicator
v. Repeat steps (i to iv)
vi. Compare error against MPE (inspection).
vii. **Record Pass / Fail**

9.2.2 Linearity

The linearity test was performed with at three different (simulated) loads, min, half max and max.

i. Zero the instrument, and add the first test load.
ii. Record the indicated value **I**
iii. Add weights to reach the second load value.
iv. Record the indicated value **I**
v. Repeat steps iv and v for each additional load value.
vi. Compare error against MPE (inspection)
vii. **Record Pass / Fail**

MPE (Inspection)	**For loads m expressed in inspection scale intervals e**			
	Class I	**Class II**	**Class III**	**Class IV**
± 1.0 e	0 ≤ m ≤ 50 000	0 ≤ m ≤ 5 000	0 ≤ m ≤ 500	0 ≤ m ≤ 50
± 2.0 e	50 000 ≤ m ≤ 200 000	5 000 ≤ m ≤ 20 000	500 ≤ m ≤ 2 000	50 ≤ m ≤ 200
± 3.0 e	200 000 < m	20 000 ≤ m ≤ 100 000	2 000 ≤ m ≤ 10 000	200 ≤ m ≤ 1 000

Table 2: NAWI MPE table (Inspection)

10 Recovery of Available Data

During the visit, it was necessary to recover as much information as possible in order to complete the control sheet, the model of which is given in Annex 1. This data was recovered through the examination of available documents (possibly copy of declaration of conformity, etc.), the visible markings on the various materials present and the information of the holders or users concerning the NAWI.

11 Project Results

The project results can be found in figure 2 to figure 20.

Ambulance Scale	2
Baby & Toddler Scale	92
Baby bed Scale	3
Baby Incubator Scale	13
Baby/Person Scale	1
Bed scale	26
Chair scale	21
Counter	3
Diaper scale	1
Lifting scale	1
Newborn Baby Weighing Scale	14
Personal Floor Scale	23
person floor scale	7
baby and teenager scale	1
Grand Total	**208**

Figure 2. Instrument Count

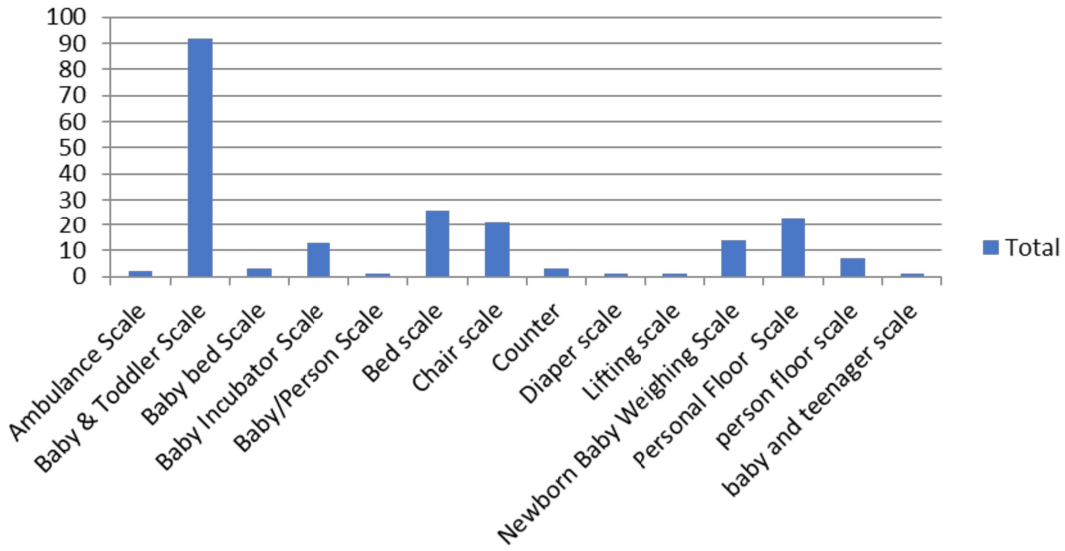

Figure 3. Instrument Type

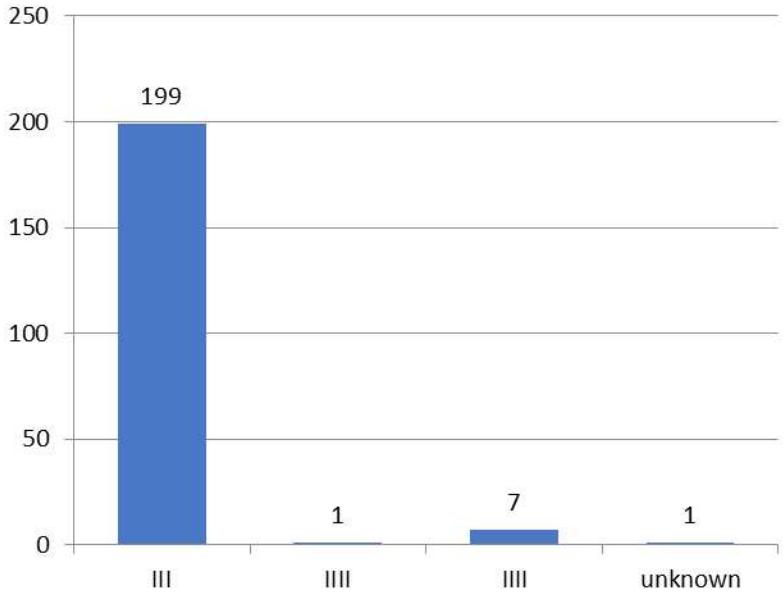

Figure 4. Accuracy Class

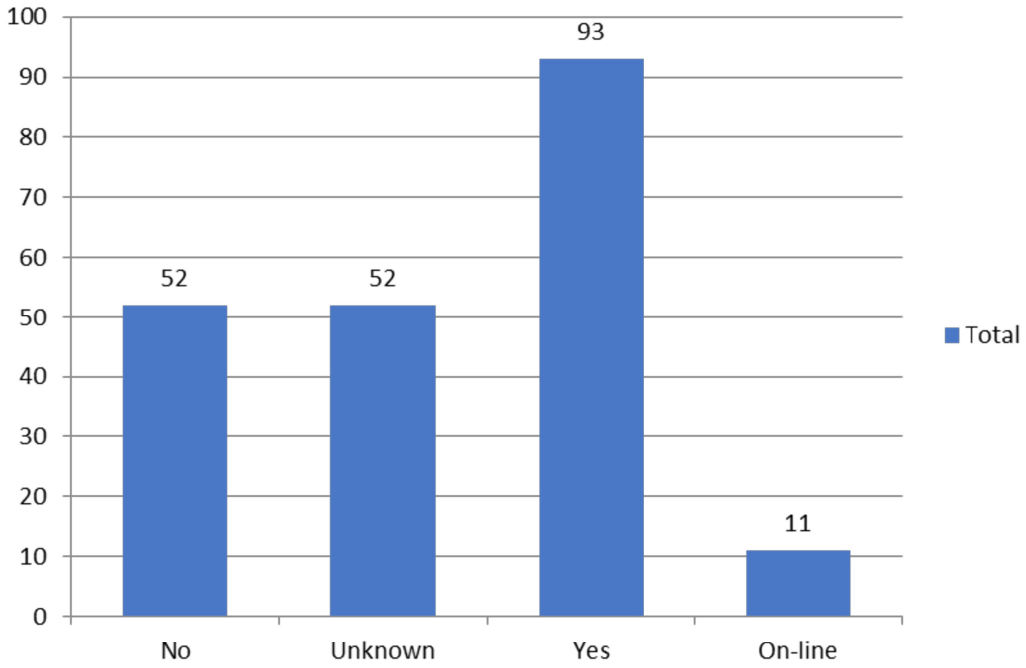

Figure 5. Declaration of Conformity

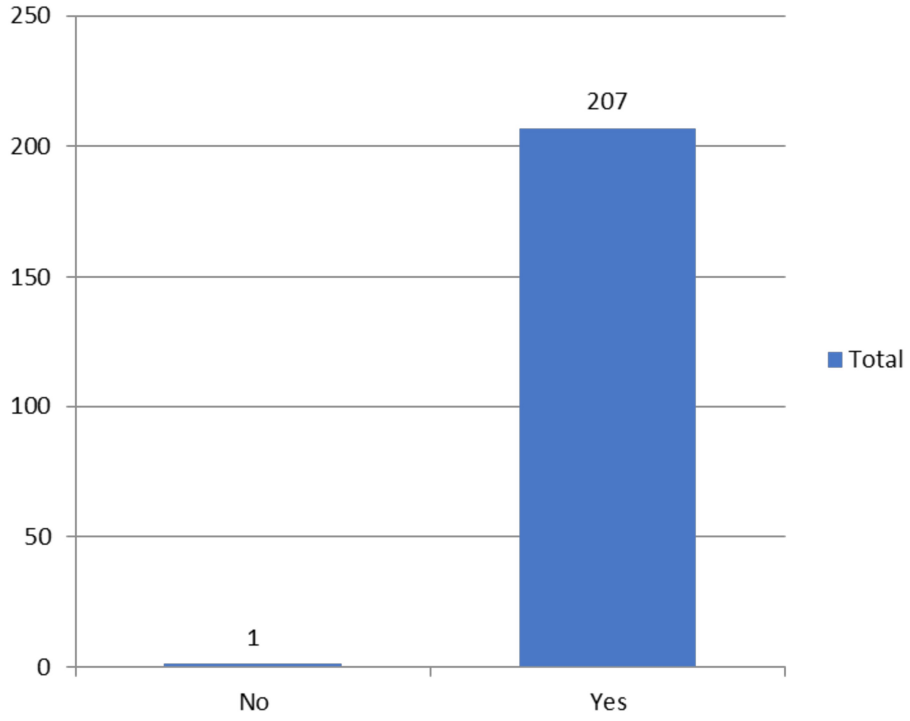

Figure 6. CE Mark

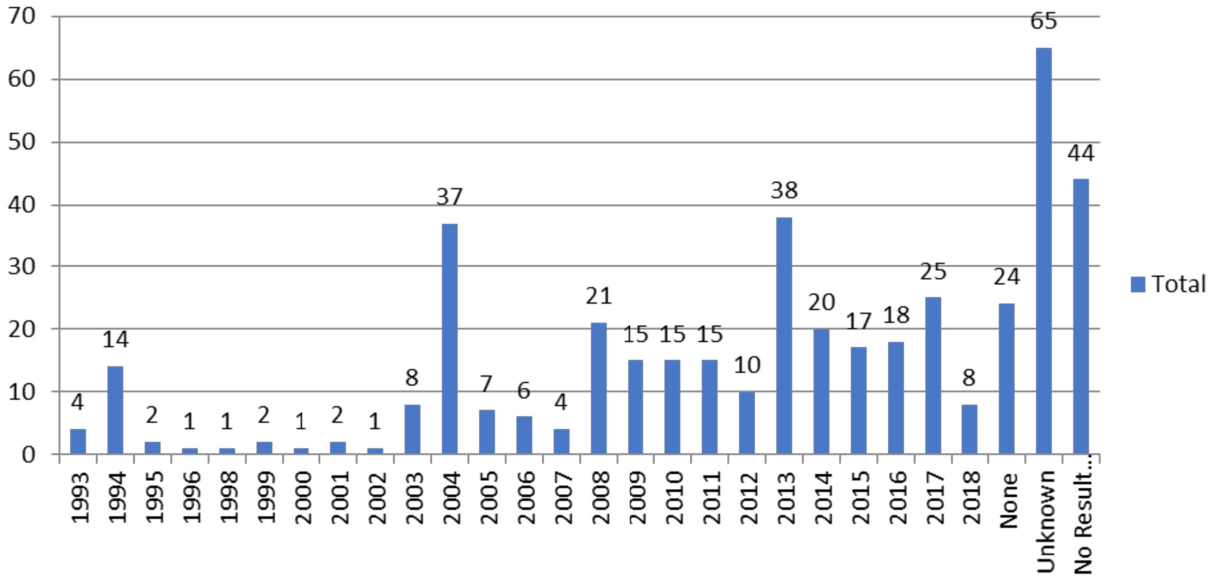

Figure 7. Year of CE Mark

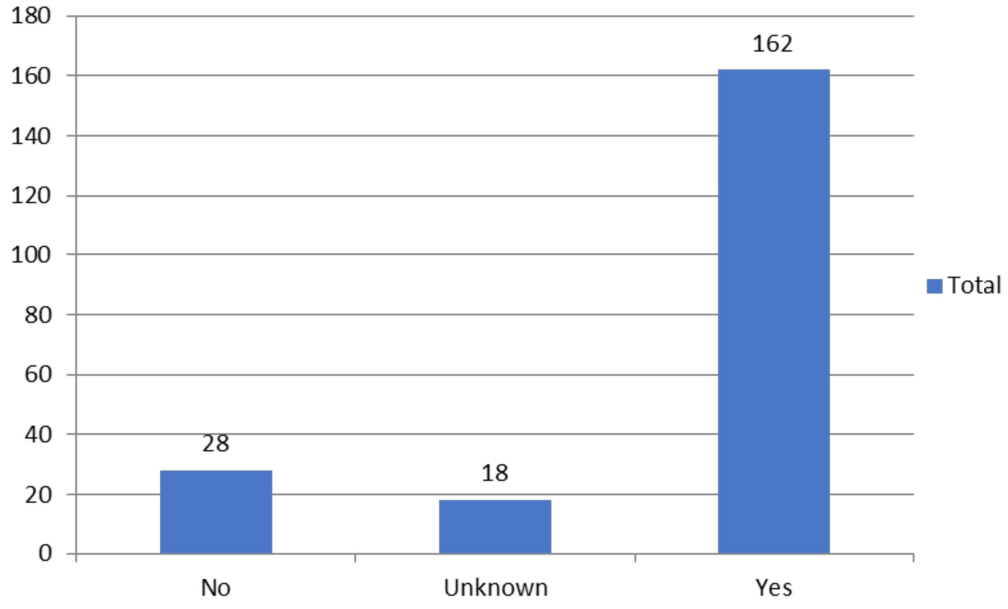

Figure 8. Sealed Per Type Approval

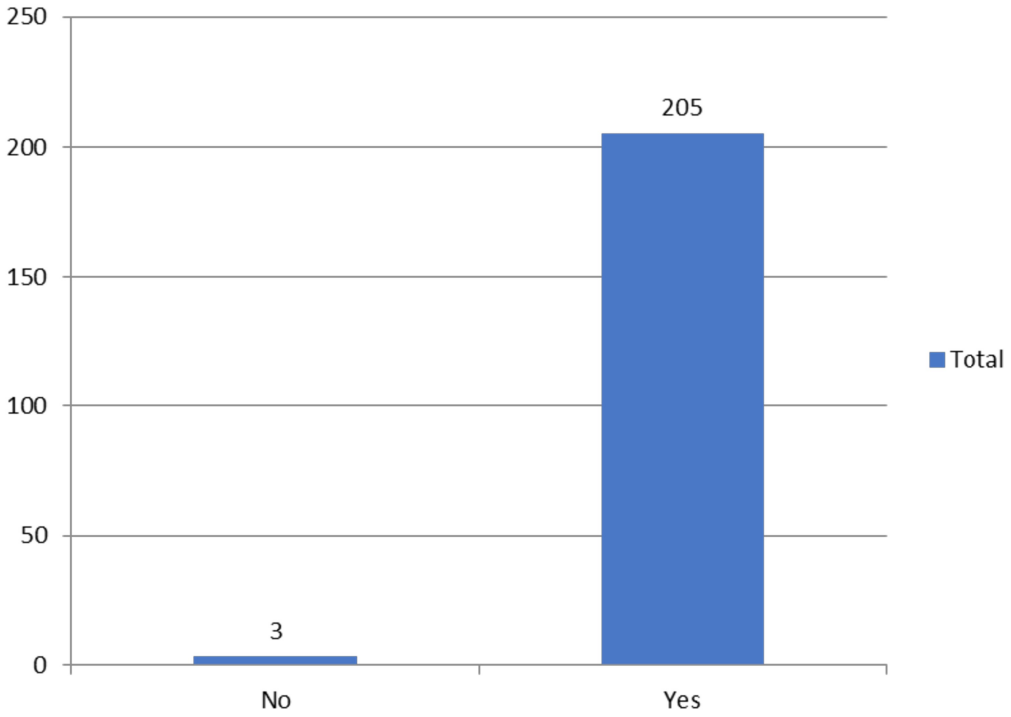

Figure 9. Data Plate

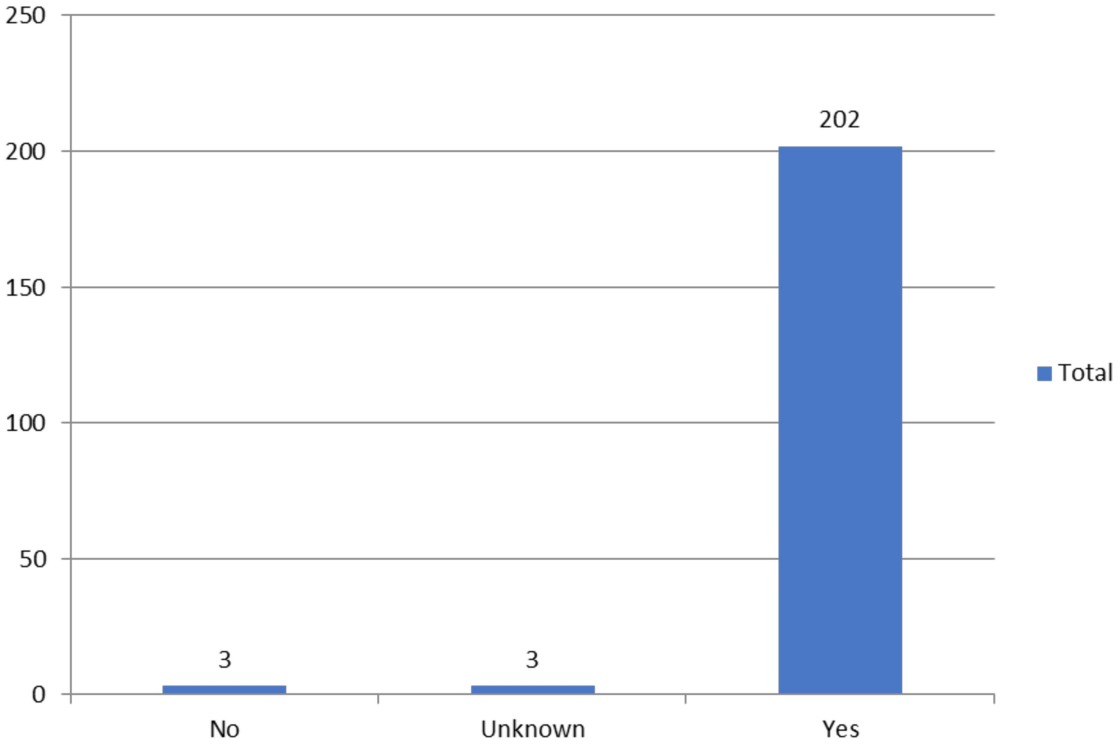

Figure 10. Notified Body Number

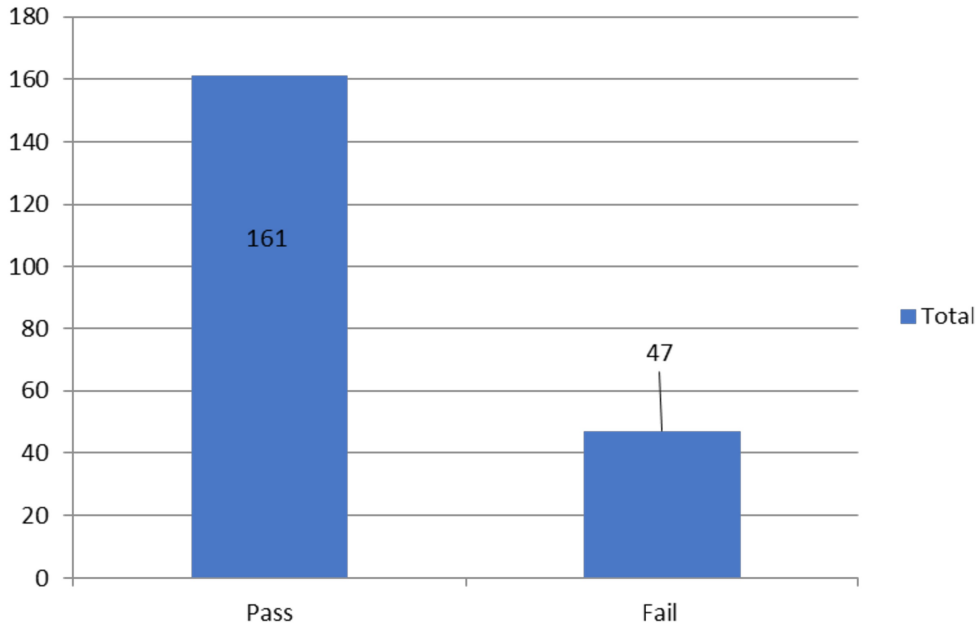

Figure 11. Visual Inspection Result

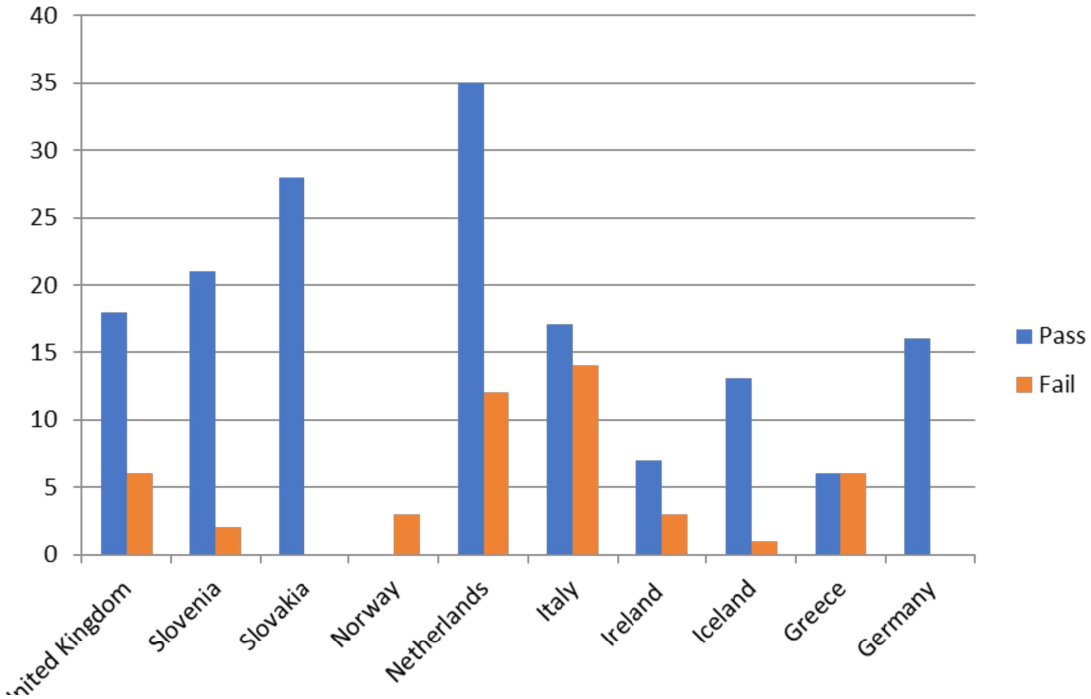

Figure 12. Visual Inspection Result by Country

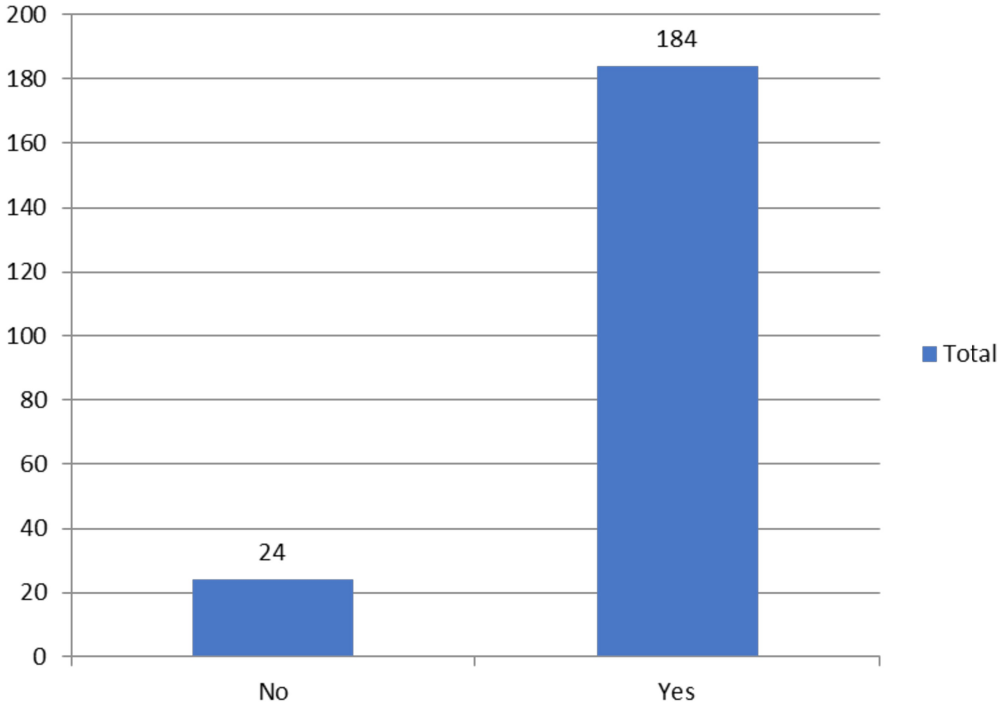

Figure 13. Metrological Inspection Result

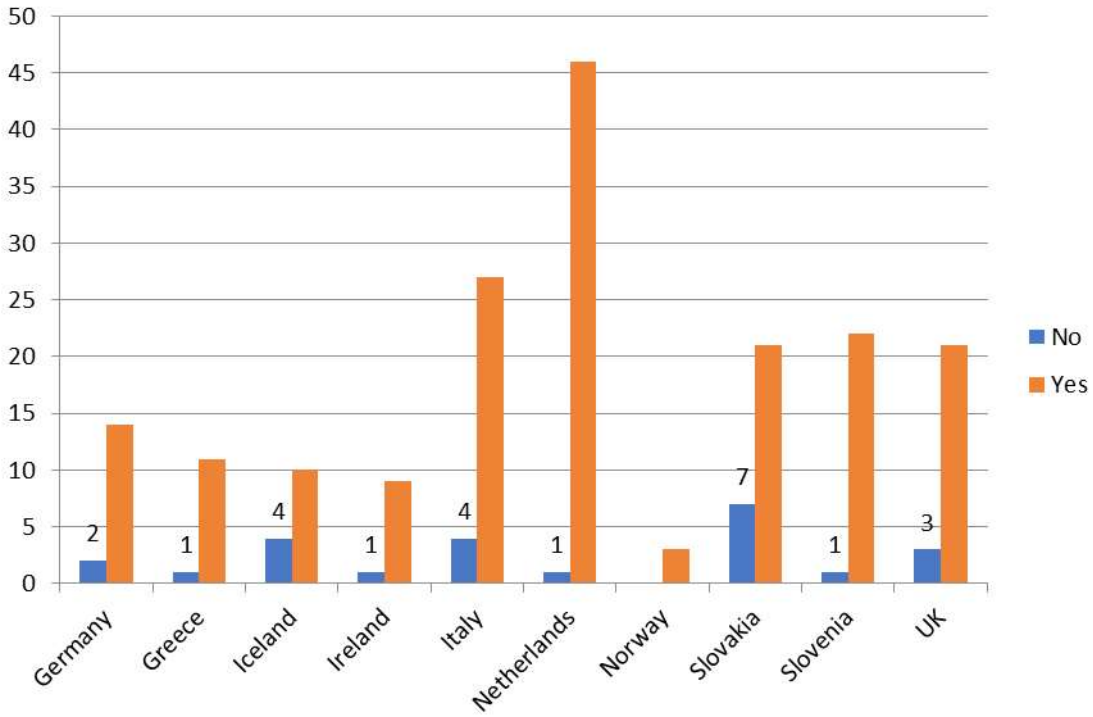

Figure 14. Metrological Result by Country

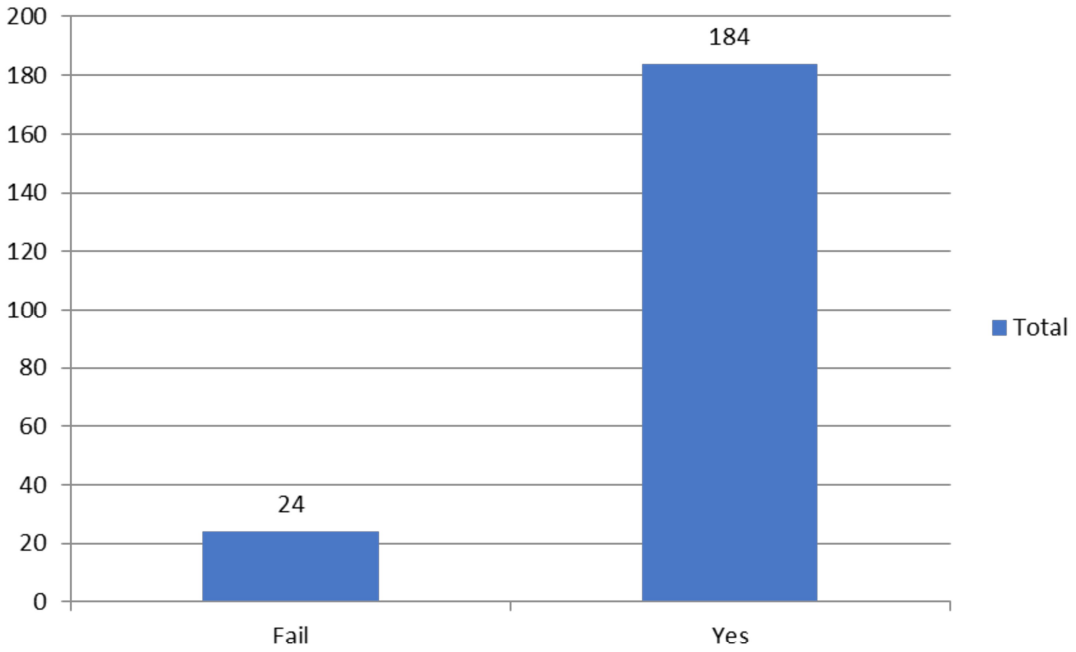

Figure 15. Linearity

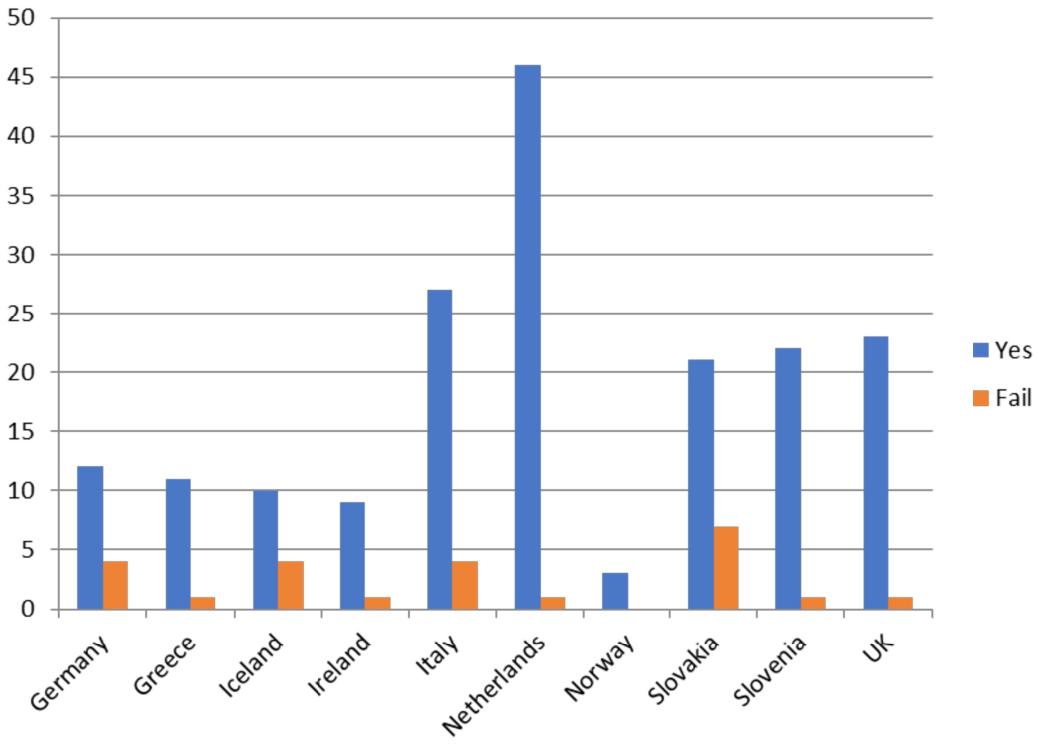

Figure 16. Linearity by Country

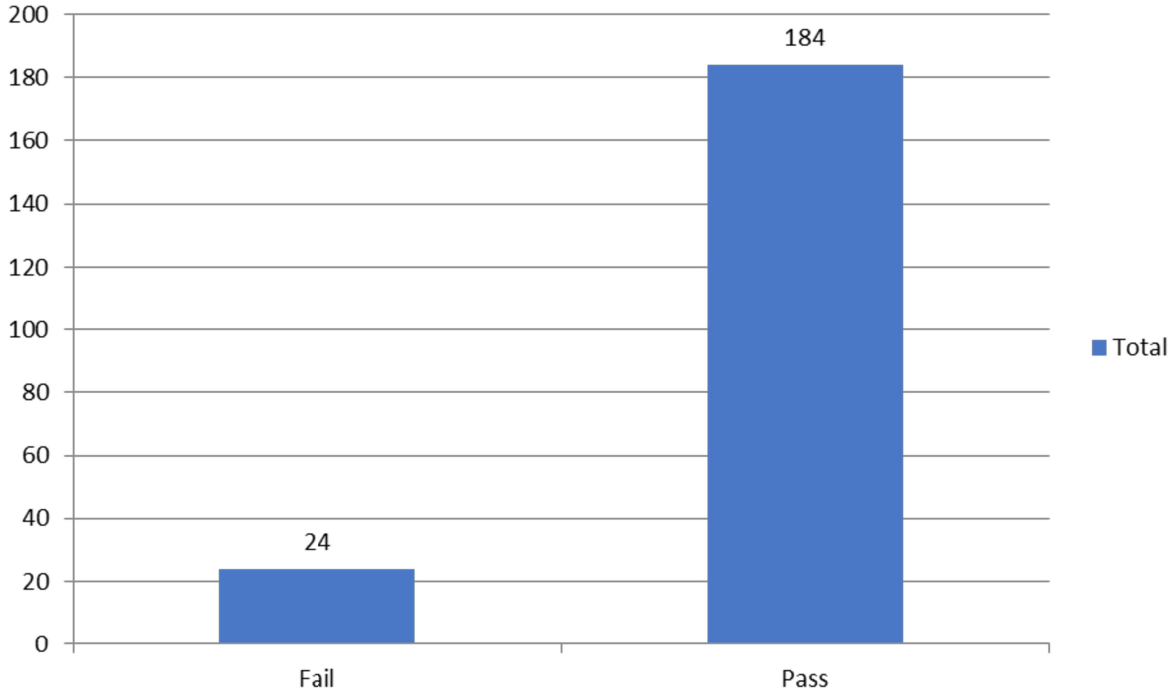

Figure 17. Repeatability

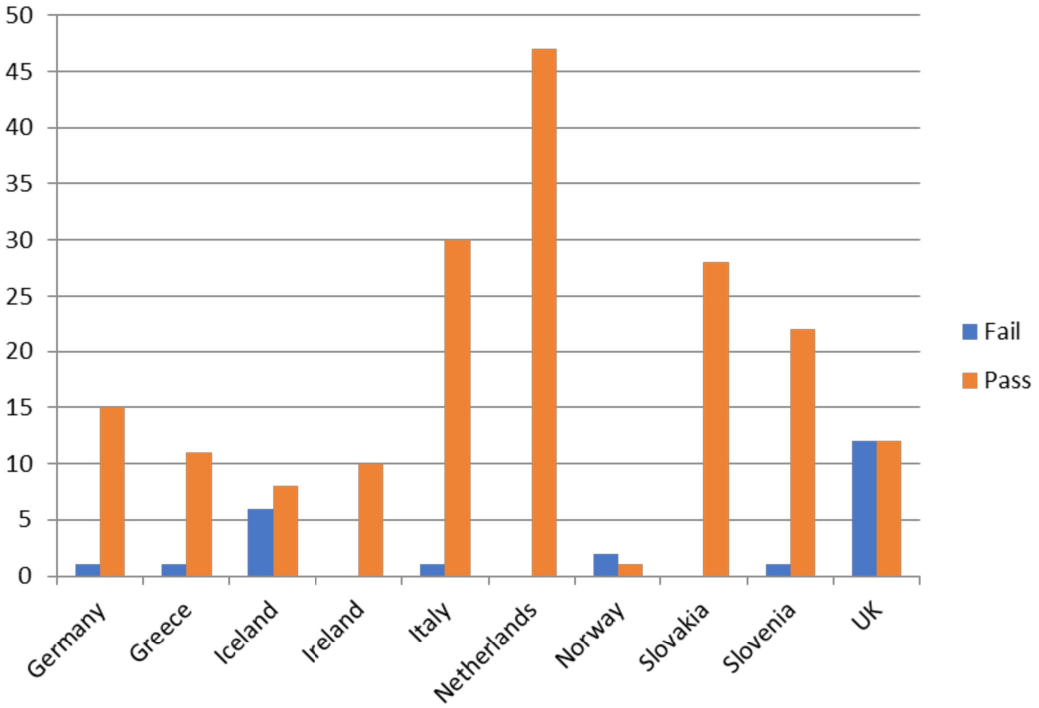

Figure 18. Repeatability by Country

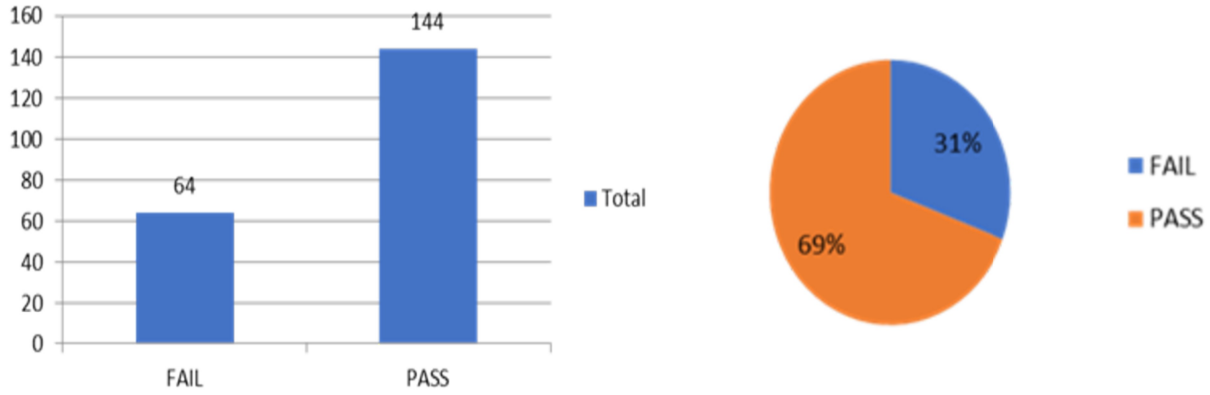

Figure 19. Overall Project Result

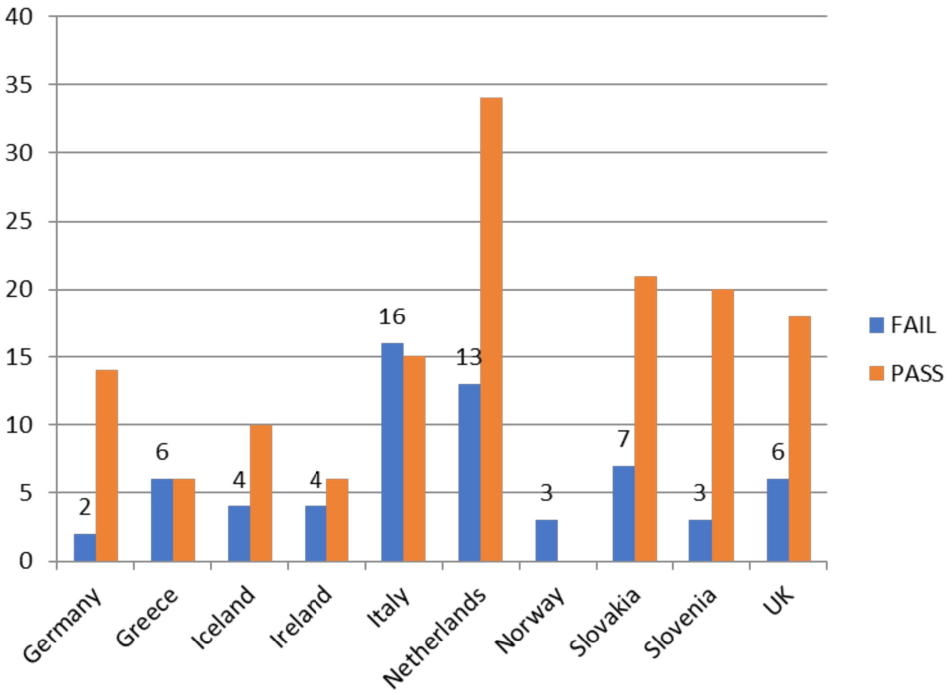

Figure 20. Overall Pass / Fail by Country

12 Project Summary

In total, 208 instruments were inspected as part of this project with an overall 69% pass rate.

13 Pre 2008 Instrument

While outside the scope of this project, 217 pre-2008 instruments were inspected by countries. Of these instruments, 78% failed the inspection while 21% passed.

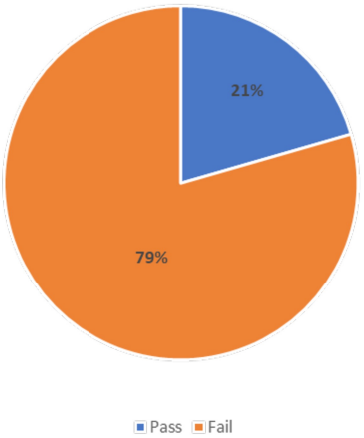

Figure 21. Pre 2008 Instruments Pass / Fail

14 Project Actions

Individual countries to address detected non-compliance in accordance with their national legislation and procedures.

Annex 1

Project Control Sheet

Examination of Medical NAWI Devices (2018 Project)

Office	
Inspector	
Date of Control	

Device Identification

Instrument Manufacturer	
Instrument Type	
Instrument Model	
Instrument Serial Number	
Min Capacity	
Max Capacity	
Verification Scale Interval e	
Accuracy Class	
Units of Measurement	
Software Version (if applicable)	

Visual

Instrument setup on a stable platform/surface	Yes ☐	No	
Instrument setup on a level platform/surface	Yes	No	
Instrument is clean and serviceable condition	Yes	No	
Instrument included in a quailty system	Yes	No	
Instrument Calibration Interval			

Conformity to Type

Number of Type Approval Certificate			
Declaration of Conformity	Yes	No	

Data Plate, Marks and Seals

Data Plate with legally relevant information	Yes	No	
CE Mark	Yes	No	
Supplementary Metrology Mark, M	Yes	No	
Notified Body Number	Yes	No	
Sealed as per Type Approval Certificate	Yes	No	

Metrological Inspection: Repeatability

		Test	Reading	
			OK	Not OK
		1	Yes	No
		2	Yes	No
Load Applied	**kg**	**3**	Yes	No
		4	Yes	No
		5	Yes	No

Metrological Inspection: Accuracy

Load Value L	Indicated Load I (g)	Additional charge until indication change ΔI (g)	Instrument Error	MPE	Instrument Compliant	
					Yes	No
					Yes	No
					Yes	No