SUMMARY REPORT ABOUT EVALUATED INSTRUCTIONS FOR USE OF RE-PROCESSABLE MEDICAL DEVICES

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INTRODUCTION

Background of the project

Preliminary market surveillance activities of European Competent Authorities for medical devices on a national level have uncovered a lack of conformity and safety of re-processable medical devices placed on the European market. This ranges from highly insufficient information for the user to information for the user provided by the manufacturer which is not based on validated processes. This also became evident during on-site visits and reports of hospitals [1] where the instructions for use (IFU) of medical devices intended to be re-processed often did not show the required information necessary for safe and adequate cleaning, disinfection and re-sterilisation (re-processing).

Conformity as given in the directives and regulations means the product fulfils all legal requirements. This shall be shown by the manufacturer of the product. For this project a subset of applicable requirements for the products under investigation has been taken and assessed. The subset selected (reprocessing and information provided therefore) is critical for its overall safety of the product and for the patient. Other aspects such as e.g. usability or suitability for given medical procedure have not been investigated under this project. So the outcome of this project cannot be used as an overall statement on clinical and technical conformity for the products under investigations.

It is evident that proper implementation of cleaning, disinfection and sterilization is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. The CDC Guideline for Disinfection and Sterilization in Healthcare Facilities from 2008 summarized from multiple studies in many countries that a lack of compliance with established guidelines for disinfection and sterilization has led to numerous outbreaks [2-9]. These incidences show how important the correct implementation of the re-processing procedures is.

Current data reveals that approx. 4 million hospitalised patients in Europe are affected by healthcare associated infections (HAI) per year and approximately 37 000 of them die as the direct result of the infection [10]. According to the Surveillance Report of the European Centre for Disease Prevention and Control the most frequent HAI types are urinary tract infections, pneumonia, surgical site infections, bloodstream infections and gastrointestinal infections – where the surgical site infections are the second most frequent healthcare-associated infection in

European hospitals [10]. There is a risk of potential underreporting of incidents due to indirect association to poor re-processing instructions.

The need of information to ensure safe and adequate re-processing is also addressed in the European legislation. Pursuant to the Medical Devices Directive 93/42/EEC (MDD), Annex I, 13.1 and specified by the harmonized standard EN 17664 the manufacturer has to provide the necessary information for the user to use the device safely and properly.
This requires – according to the harmonized standard EN ISO 17664 - that at least one validated reprocessing procedure has been specified (and assessed) by the manufacturer and is described in the IFU.
Another important justification for carrying out this project is the fact that the majority of re-processable surgical instruments fall within the lowest risk classification due to the classification rules of the Medical Device Directive 93/42/EEC. The significance of this is that the manufacturer takes sole responsible for ensuring regulatory compliance, whereas for devices in a higher classification (IIa, IIb & III), a notified body is required to perform a conformity assessment prior to the device receiving certification. This lack of extra scrutiny could therefore lead to lower quality IFUs.

Therefore the European Competent Authorities for medical devices in Austria, Belgium, Croatia, Hungary, Ireland, Italy, Norway, Portugal, Slovakia, Spain, Sweden and the United Kingdom undertook an assessment of the market and to evaluate whether the instructions for use of medical devices intended to be re-processed fulfil the legal requirements. This was carried out in accordance with Member States' market surveillance obligations under the Regulation on Accreditation and Market Surveillance (765/2008/EEC).

ACKNOWLEDGEMENTS

We acknowledge the efforts to foster joint market surveillance actions and activities, within this project in the field of medical devices, by the EU-Commission and their supporting activities.

MATERIALS and METHODS

In order to evaluate the compliance of the IFU of medical devices intended to be re-processed the task was divided into following parts:

I. Identification of appropriate reusable medical devices

Due to the broad field of re-processable medical devices, criteria had to be specified to select the appropriate device types and to be able to evaluate the status in the market. To ensure the practical perspective is included the following representative Health Care professionals were asked for input by the Portuguese Competent Authority: Association of Gastroenterology and Endoscopy Nurses (APEEGAST), the Operating Room Nurses Association (AESOP) and the Sterilization Association (ANES).

Based on the outcome of the consultation of the above mentioned Health Care professionals and the input from the project partners suitable selection criteria and medical device types were defined.

Defined selection criteria:

a) Most often found in the hospital units - widely used
b) Intended to be invasive and/or for surgical use – commonly used in surgical procedures in different fields (e.g. cardiology, thoracic, orthopaedic, neurology, gastroenterology)
c) Challenging in cleaning, disinfecting or sterilising due to the structure of the device – e.g. surface, geometry or medical device composition
d) Steam sterilisable – because steam sterilisation is the most commonly used sterilisation process in the hospital

Defined medical device types:

MEDICAL DEVICE TYPE	RISK CLASS[1]
Surgical retractors	I, IIa and III
Surgical needles	I, IIa, IIb and III
Drills and burs	I, IIa, IIb and III
Scalpel handles	I, IIa and IIb
Clamps	I, IIa, IIb and III
Forceps	I, IIa, IIb and III
Needle holders	I, IIa and IIb
Surgical saws	I, IIa and IIb
Probes	I, Im, IIa, IIb, III
Scissors	I, IIa, IIb and III
Trocars	I, IIa and IIb
Curettes	I, IIa and IIb
Endoscopy accessories (such as forceps, probes, knives, snares)	I, Im[2], IIa, IIb and III

Table 1: *Defined medical device types based on the previously defined selection criteria*

For explanation: According to the Council Directive 93/42/EEC (page 4) medical devices are grouped into four product classes, based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices. Risk class I products (the lowest risk class) may be placed on the market without the involvement of a notified body.

II. Identification of the corresponding economic operators

Having defined the appropriate re-processable medical device types, the related economic operators were identified. The search was limited to economic operators based in the territory of the participating member states (AT, BE, HR, IT, NO, IE, HU, SE, ES, PT, SK, UK) and some collaborating Member States (DE, NL and CH). The definition of economic operators applies to European manufacturers, authorised

[1] Within each medical devices type, different risk classes might be found, depending on the intended use, according to database or Portugal search.

[2] Im – risk class I with measuring function

representatives, who are acting with regard to the manufacturer's obligation under the Medical Devices Directive, and their distributors. It was decided that participating member states having no manufacturer or authorised representative meeting the selection criteria shall include distributors of manufacturers/authorised representatives of collaborating member states. It has to be noted that presently there is no centralized and complete database where all manufacturers placing products on the common market are listed. So this search had to be done on national databases in cooperation between all participating member states, and the results had to be pooled and aligned.

III. Tool to receive information from the market (checklist 1)

To get the necessary information from the economic operators for investigating if the instruction for use contains all required information necessary for safe re-processing, a questionnaire (in the following: "checklist 1") and a cover letter were developed. Checklist 1 (Annex 1) is based on the harmonized European standard EN ISO 17664 (title: "Sterilisation of medical devices - Information to be provided by the manufacturer for the processing of re-sterilisable medical devices"). This standard is intended to aid manufacturers in their compliance with section 13 of the essential requirements as set out in Annex I of the Medical Devices Directive 93/42/EEC [Information to be provided by the manufacturer]. The use of harmonised standards is not mandatory however EN ISO 17664 is considered as the state of the art with regards to information provided by the manufacturers in their IFU. The cover letter was developed to provide background information and guidance on how to complete the checklist.

The cover letter and checklist 1 were translated into the Member States' national languages and sent out to the selected economic operators by each participating Member State.

The checklist consists of 59 questions addressing the information considered necessary for safe re-processing (see checklist 1, Annex 1). The economic operators were asked to answer the questions by selecting following answers via drop down menu and to reference the corresponding instructions for use (IFU):

ANSWER	DESCRIPTION OF THE ANSWER
Yes	Information is included in the IFU
No	Information is not included in the IFU
n.a.	Not applicable

Table 2: *Answers to be selected by the economic operators*

The following information was also requested: The size of the company, the medical device type (Table 1) and the risk class of the device.

The size of the company was requested by using a drop down menu to select “small company” for less than 50 employees, “medium company” for 50-249 employees or “large company” for 250 and more employees.

It was requested to complete the checklist for one representative product for each of the defined medical device type and to submit the associated instructions for use.

IV. Checking the compliance of the manufacturers’ re-processing instructions

The basis of a valid assessment performed by twelve Member States is a harmonised approach. First of all every participating Member States was brought up to the same level of knowledge by organising a multi-day training course about re-processing. To guarantee a harmonised assessment regarding the compliance of the manufacturers’ re-processing instructions, open questions were collected and answered by all participants, using the team collaboration software “Confluence” (Atlassian). Questions answered during face to face meetings were also collected in “Confluence”.

Checklists and corresponding instructions for use (IFU) were assessed by each participating Member State regarding compliance to the MDD 93/42/EEC, Annex I, 13.1 according to following scoring system:

SCORE	DESCRIPTION OF THE SCORE
0	No data provided/ not acceptable answers (e.g.: references, which are unverifiable/ data provided but not commonly used in Europe / recommendations which do not meet EN standards)
1	Acceptable answers
n.a.	Not applicable

Table 3: *Assessment scheme to evaluate the economic operators’ responses and whether the provided information necessary for safe re-processing is compliant to the MDD 93/42/EEC, Annex I, 13.1*

V. Analysis of the assessment results of the economic operators' responses

For statistical analysis of the assessment of the manufacturers' responses the statistic program SAS 9.3 was used. For the comparison of company sizes and for the comparison of risk class I devices with devices with risk classes higher than I following statistical test was used: "logistic regression". "Monte Carlo estimates for Fisher's exact test" were used to check whether there is a significant difference in the compliance between the different types of medical devices.
Results with a p-value of less than 0.05 are classified as "significant", whereas a p-value of less than 0.001 are classified as "highly significant".

RESULTS

I. Identification of appropriate reusable medical devices

248 checklists - each presenting a defined type of medical device - were received and evaluated. The most common (>10%) medical device types are: Forceps (34/248; 13.7%), drills and burs (32/248; 12.9%) and surgical retractors (25/248; 10.1%). Table 4 below shows the number of received checklists aggregated by type of medical device.

MEDICAL DEVICE TYPE	NUMBER OF RECEIVED CHECKLISTS (n=248)
Forceps	34
Drills and Burs	32
Surgical retractors	25
Scissors	22
Endoscopy accessories	22
Probes	18
Curettes	18
Scalpel Handles	17
Needle holders	16
Clamps	15
Trocars	13
Surgical saws	11
Surgical needles	5

Table 4: *Number of checklists presented on types of medical device*

II. Identification of the corresponding economic operators

The checklist was sent out to 111 economic operators, following within the strategy defined. Valid responses from 98 economic operators were received (88.3%). The remaining amount of 13 economic operators could not be assessed due to various causes like the economic operators being out of scope or non-existent.

Therefore 98 economic operators were assessed and evaluated. The presented results refer to 98 economic operators who completed a total of 248 checklists (Table 4).

III. Description of economic operators and received checklists

The company size of the economic operators is described below (Table 5). The most common company size was the small company with 73.5%; whereas medium and large company sizes were represented with 13.3% each.

COMPANY SIZE	NUMBER OF COMPANIES (n=98)
Small company (< 50 employees)	72
Medium company (50-249 employees)	13
Large company (> 250 employees)	13

Table 5: *Number of companies per company size*

The majority of companies presented one or two medical device types (i.e. number of checklists): 61 companies with 1 device (62.2%), 10 companies with 2 devices (10.2%). A total of 27 companies had more than 2 (up to 12) medical device types. The company size showed differences in the average number of medical device types (i.e. number of checklists included in this assessment; Table 6). Large companies had an average of 4.4 checklists, significantly higher (p=0.009) compared to small companies (mean 2.2 checklists). There was also a trend toward significance in the difference between large companies and medium companies (p=0.085).

Company Size	Number of companies	Number of checklists		
		Total	Mean	Range
Small company	72	158	2.2	[1 - 12]
Medium company	13	33	2.5	[1 - 11]
Large company	13	57	4.4	[1 - 12]
Total	**98**	**248**	-	-

Table 6: *Calculation of the mean value of checklists completed per company size*

IV. Checking the compliance of the manufacturers' re-processing instructions

Overview

The checklist consists of 59 questions of which only 47 questions were evaluated. 12 questions were excluded from the evaluation of compliance, as they collected general information, or collected information on the validation process not considered essential information for users.

Analysing the compliance of the manufacturers' re-processing instructions, the overview shows clearly that much of the required information necessary for safe re-processing is not compliant to the requirements of the Medical Devices Directive (MDD) 93/42/EEC, Annex I, 13.1 and the specifications of the harmonised standard EN 17664.

32 of 47 questions (68.0%) show a non-compliance rate of 50% and higher, including primarily the following topics:

- Permitted number of reprocessing cycles
- Maximum time defined between use and cleaning
- Manual and automated cleaning & disinfection
- Drying
- Packaging
- Sterilization
- Instructions on medical device transport conditions

12 of 47 questions (25.5%) show a non-compliance rate of 20% to 50%, including the following topics:

- Provided date of release for the Instructions for use
- Catalogue number / Reference number and device description provided
- End of life: Imperative conditions for not continuing to use the medical device provided
- Preparation for cleaning: Instructions provided in case preparation prior to cleaning is necessary
- Instructions for disassembly/re-assembly of the medical device provided
- Provided information regarding equipment to be used for manual cleaning
- Specified water quality for manual cleaning
- Maintenance: Information on the time or condition of storage of the reprocessed medical device(s) prior to use provided

3 of 47 questions (6.4%) show a non-compliance rate of 0% to 20%, including the following topics:

- Warnings given regarding inappropriate chemicals or points of particular attention
- Required temperature and minimum holding time of the steam during sterilization

The 50% rate was selected for easier reading of the statistics. This does not correlate to the extent and valuation of the detected non-compliances.

The highest proportion of non-compliant answers can be clearly seen for the provided limits and required monitoring of chemical residues on the device. The high non-compliance rate (≥ 83%) in this area is based on the fact that almost no information was provided at all. This is followed by the lack of specification of water quality to be taken for sterilising the medical devices (83%) and process temperature + exposure time for manual disinfection (79%) (Figure 1).

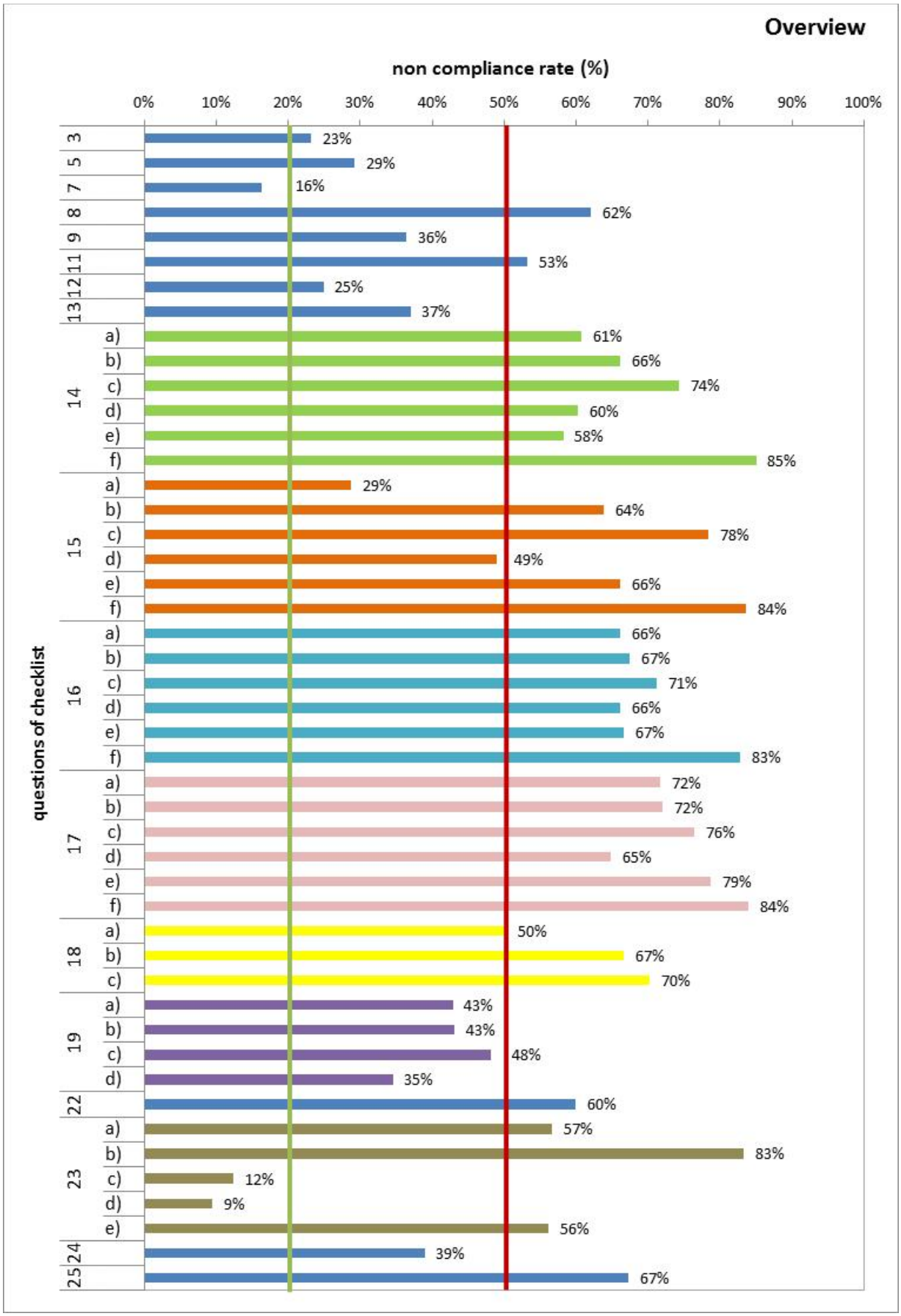

Fig. 1: *Overview of non-compliant information provided in the instructions for use (IFU). Assessment based on 248 checklists.*

Legend: Overview

Questions of the checklist:

1 – Name and address of the manufacturer
2 – Name and address of the European Authorized Representative
3 – Instructions for use: Date of release
4 – Method: At least one validated method for reprocessing provided
5 – Reusable device listed by catalogue number or reference number and device description available
6 – Symbol: Any symbols related to reprocessing used
7 – Warnings: Warnings regarding inappropriate chemicals, points of particular attention
8 – Limitations on reprocessing: Permitted number of reprocessing cycles
9 – End of life: Imperative conditions for not continuing to use the medical device
10 – General aspects: Identification of other specific materials or products needed for the reprocessing
11 – Time: Maximum time between use and cleaning defined
12 – Preparation for cleaning: Instructions provided in case preparation prior to cleaning is necessary
13 – Instructions for disassembly/re-assembly of the medical device

14 – Cleaning: Automated	a) Equipment to be used b) Identification of chemicals c) Concentration of chemicals d) Specification of water quality e) Process temperature + exposure time f) Limits and monitoring of chemical residues on the device g) Description of effectiveness of cleaning/disinfection
15 – Cleaning: Manual	a) to g) see Cleaning: Automated
16 – Disinfection: Automated	a) to g) see Cleaning: Automated
17 – Disinfection: Manual	a) to g) see Cleaning: Automated
18 – Drying	a) Equipment b) Drying agent c) Temperature and exposure time
19 – Maintenance	a) Performance criteria for the medical device to ensure safe use b) Method to be used for adjustment/calibration of the medical device c) Description of replacement of components d) Description of the lubrication to be used

20 – Repair: Are situations specified where the device repair must be performed only by the manufacturer, requiring return
21 – Containing: Are special containers necessary for sterilization
22 – Packaging: Are special packaging for maintaining sterility necessary

23 – Sterilisation	a) Equipment to be used b) Specification of water quality c) Required temperature d) Minimum holding time of the steam e) Required pressure

24 – Storage: Information on the time or condition of storage of the reprocessed medical device(s) prior to use provided
25 – Transport: Instruction on medical device transport conditions, including carrying containers given
26 – Contact details for further information from the manufacturer or EAR stated

Note: The questions in grey were not included in the evalution of compliance.

Comparison of medical device types

The various medical device types show no significant difference[3] in observed non-compliancy for the majority of questions (Figure 2-14). The only statistically significant differences are observed for question 5 (device listed by catalogue number or reference number) (p=0.0037), question 13 (instructions for disassembly/re-assembly of the medical device) (p=0.0039) and question 19c) (description of replacement of components) (p=0.0285).
The following medical devices types show a non-compliance rate of less than 50% for question 5: trocars, forceps, scalpel handles, drills and burs, endoscopy accessories, probes.

For question 13 the following medical device types show a non-compliance rate of less than 50%: scalpel handles, curettes, drills and burs, surgical needles, endoscopy accessories, probes, surgical saws.
For question 19c) the following medical device types show a non-compliance rate of less than 50%: surgical needles, endoscopy accessories, surgical retractors, drills and burs, probes, surgical saws.

When analysing in which aspects the non-compliance rate is equal to or higher than 50% of a certain medical device type, it can be seen that this is the case for:
38 questions for scissors (80.9%), 35 questions for needle holders (74.5%), 35 questions for trocars (74.5%), 33 questions for forceps (70.2%), 32 questions for scalpel handles (68.1%), 31 questions for curettes (66%), 30 questions for clamps (63.8%), 30 questions for surgical retractors (63.8%), 29 questions for drills and burs (61.7%), 29 questions for surgical needles (61.7%), 28 questions for endoscopy accessories (59.6%), 28 questions for probes (59.6%) and 27 questions for surgical saws (57.4%).

[3] Refer to page 9, „V. Analysis of the assessment results of the economic operators' responses"

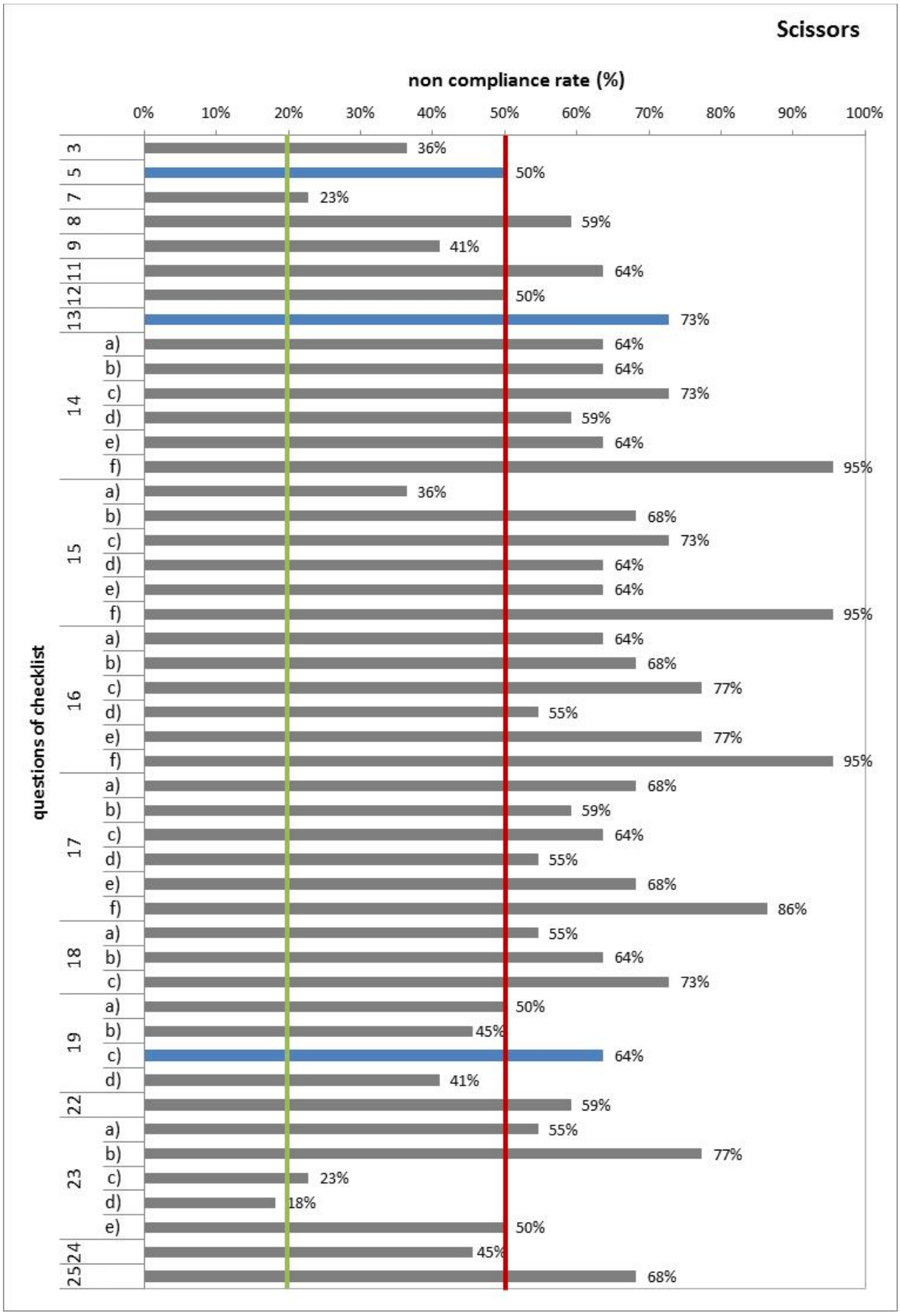

Fig. 2: *Non-compliant information provided in the IFU of scissors.*
Bars in blue = significant difference to other medical devices types.

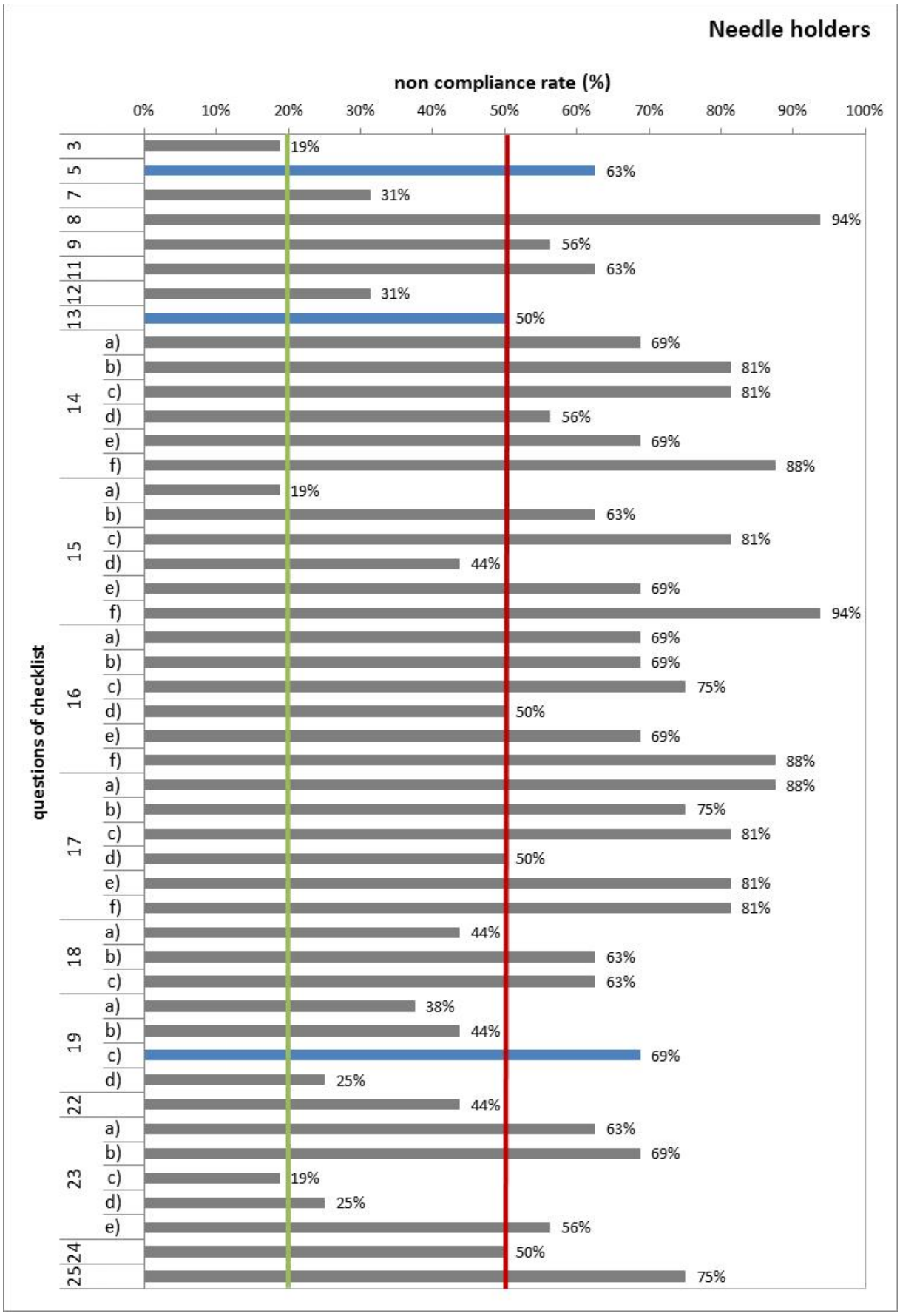

Fig. 3: *Non-compliant information provided in the IFU of needle holders. Bars in blue = significant difference to other medical devices types.*

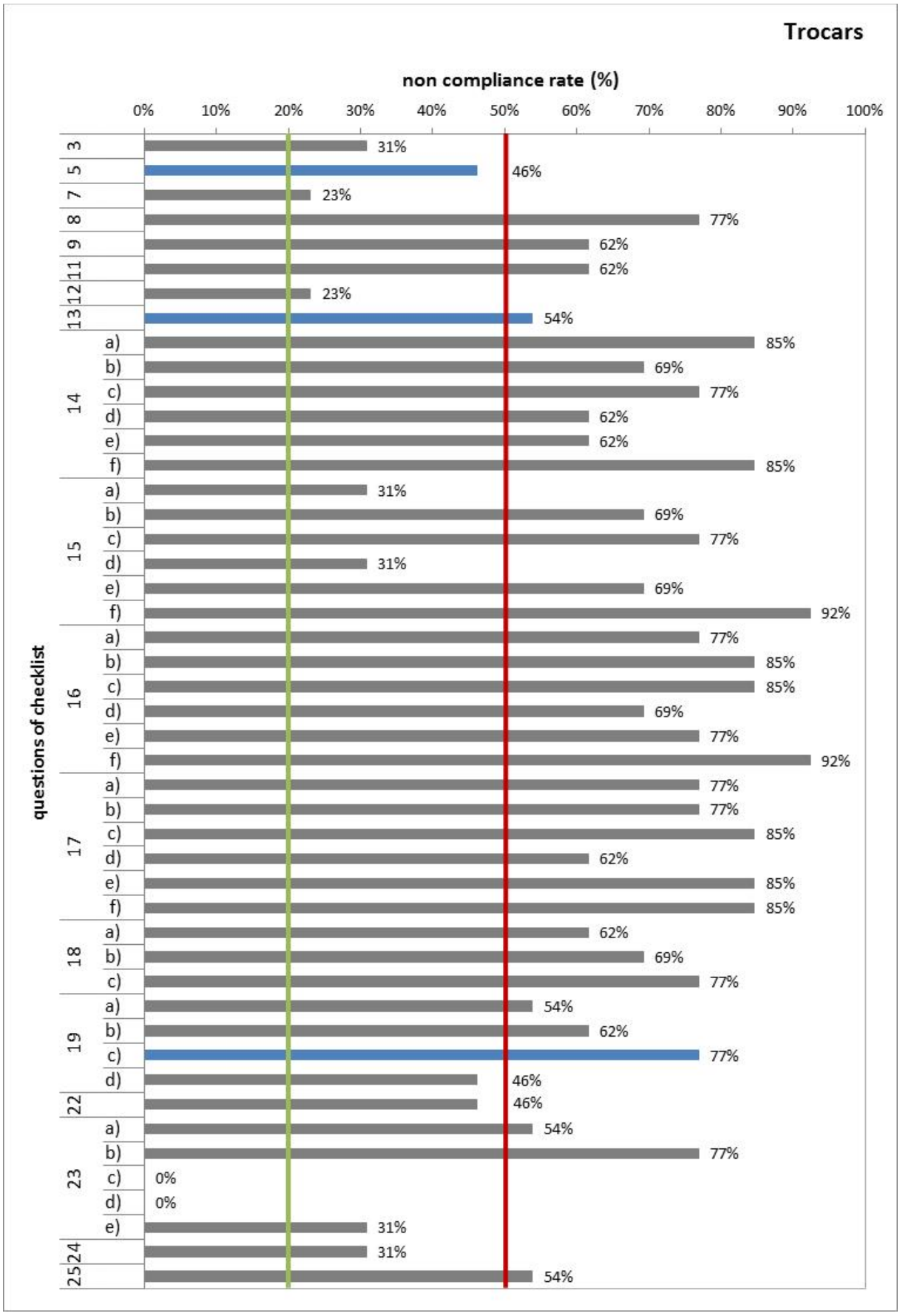

Fig. 4: *Non-compliant information provided in the IFU of trocars.*
Bars in blue = significant difference to other medical devices types.

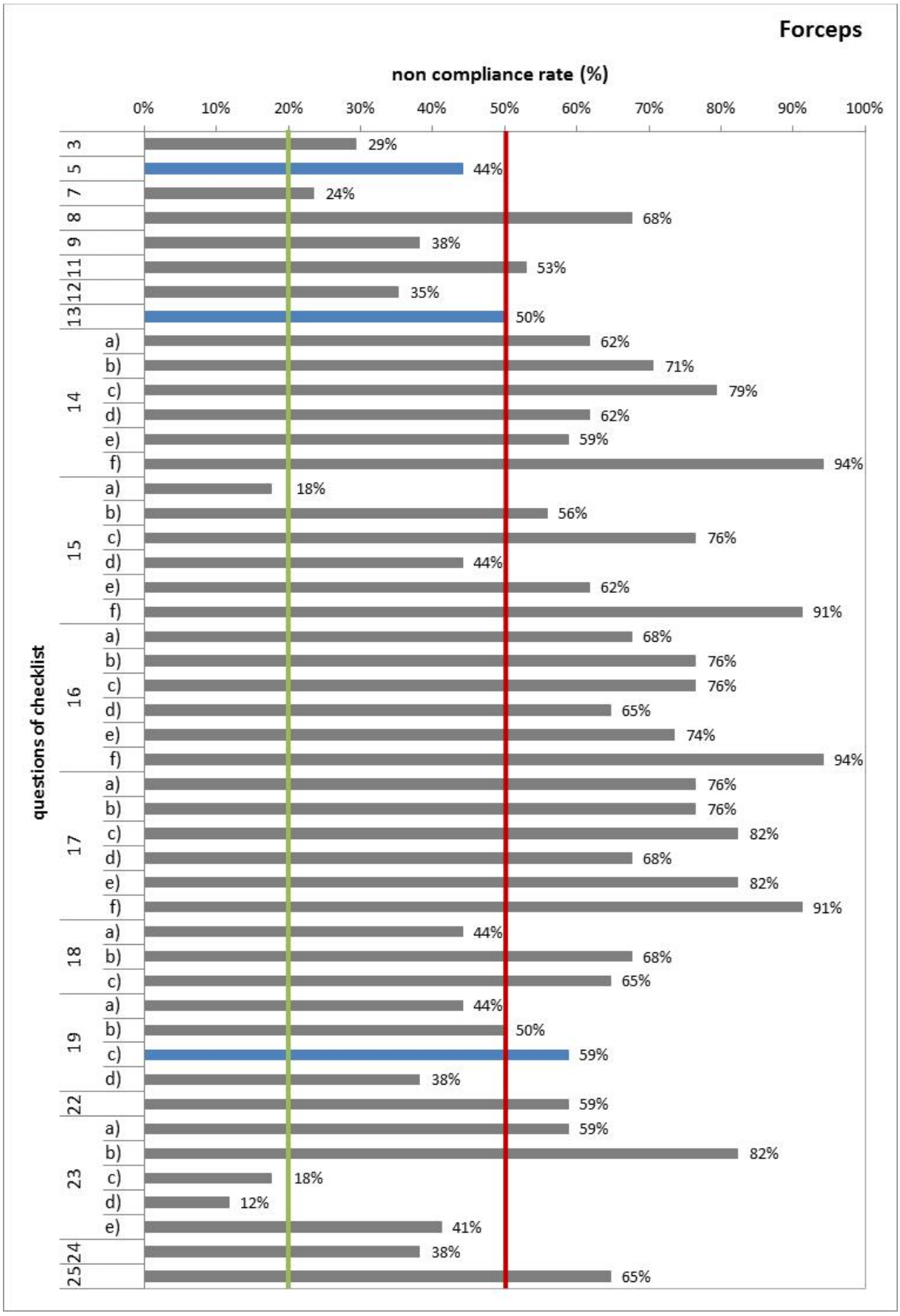

Fig. 5: *Non-compliant information provided in the IFU of forceps.*
Bars in blue = significant difference to other medical devices types.

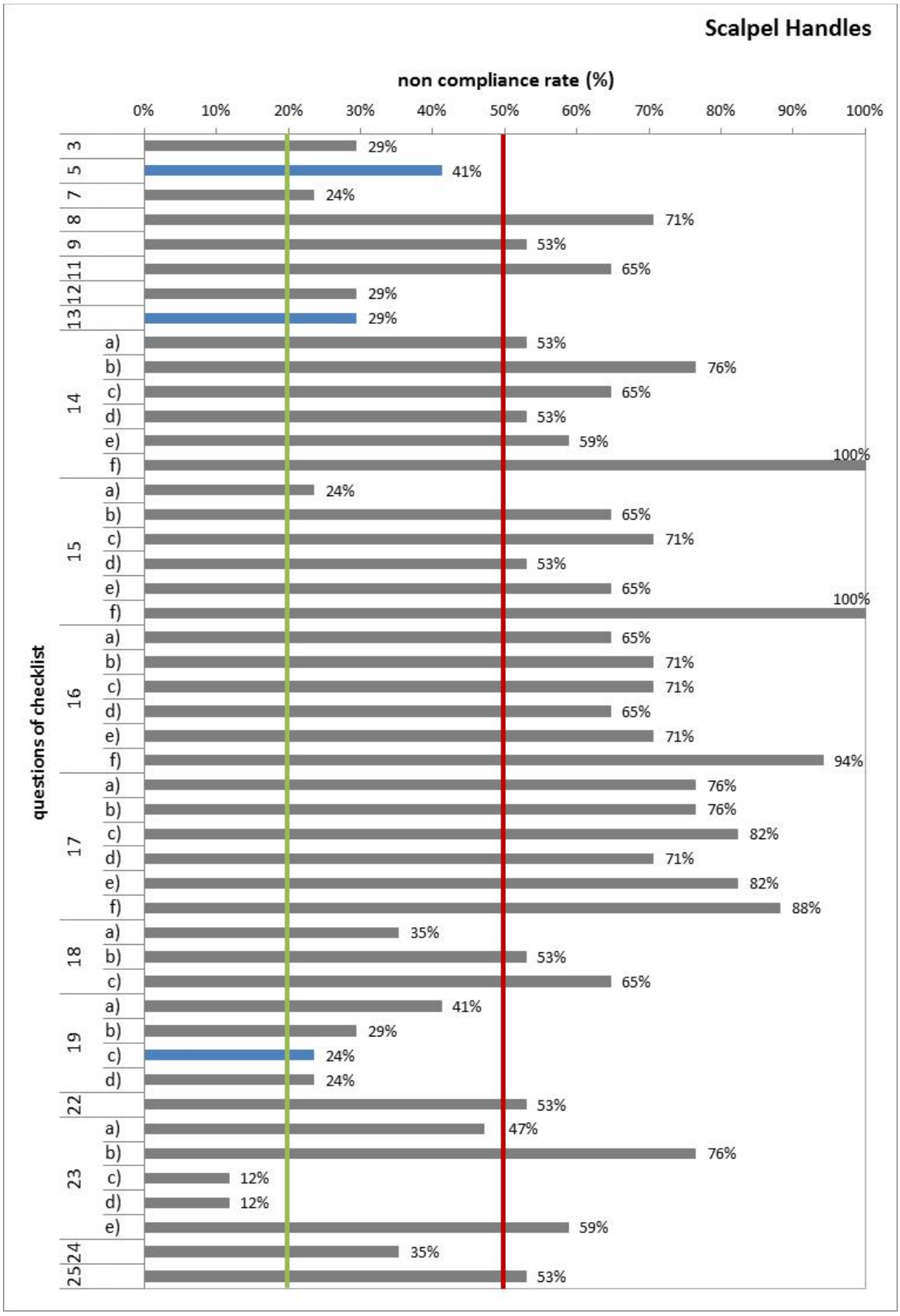

Fig. 6: *Non-compliant information provided in the IFU of scalpel handles. Bars in blue = significant difference to other medical devices types.*

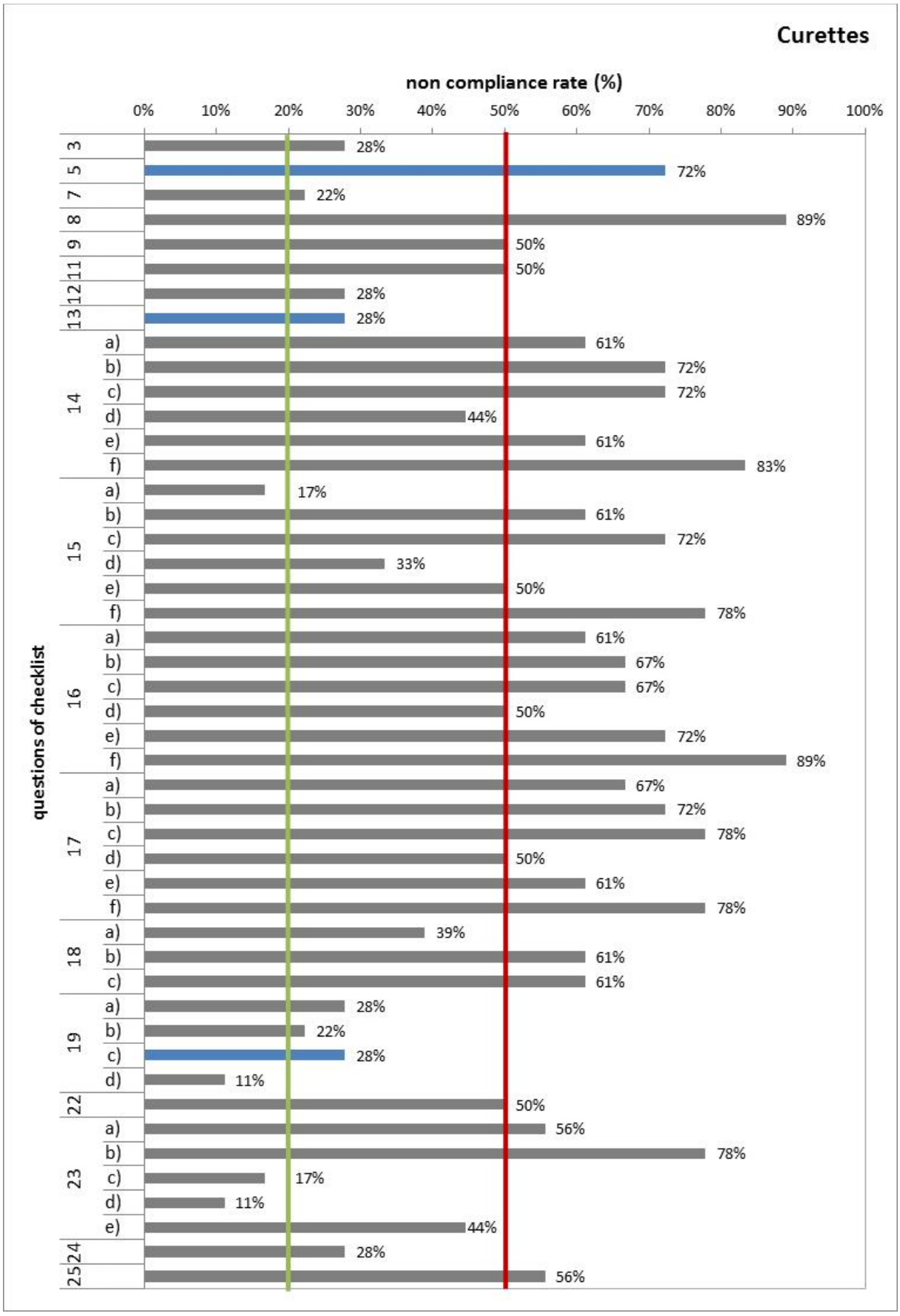

Fig. 7: *Non-compliant information provided in the IFU of curettes.*
Bars in blue = significant difference to other medical devices types.

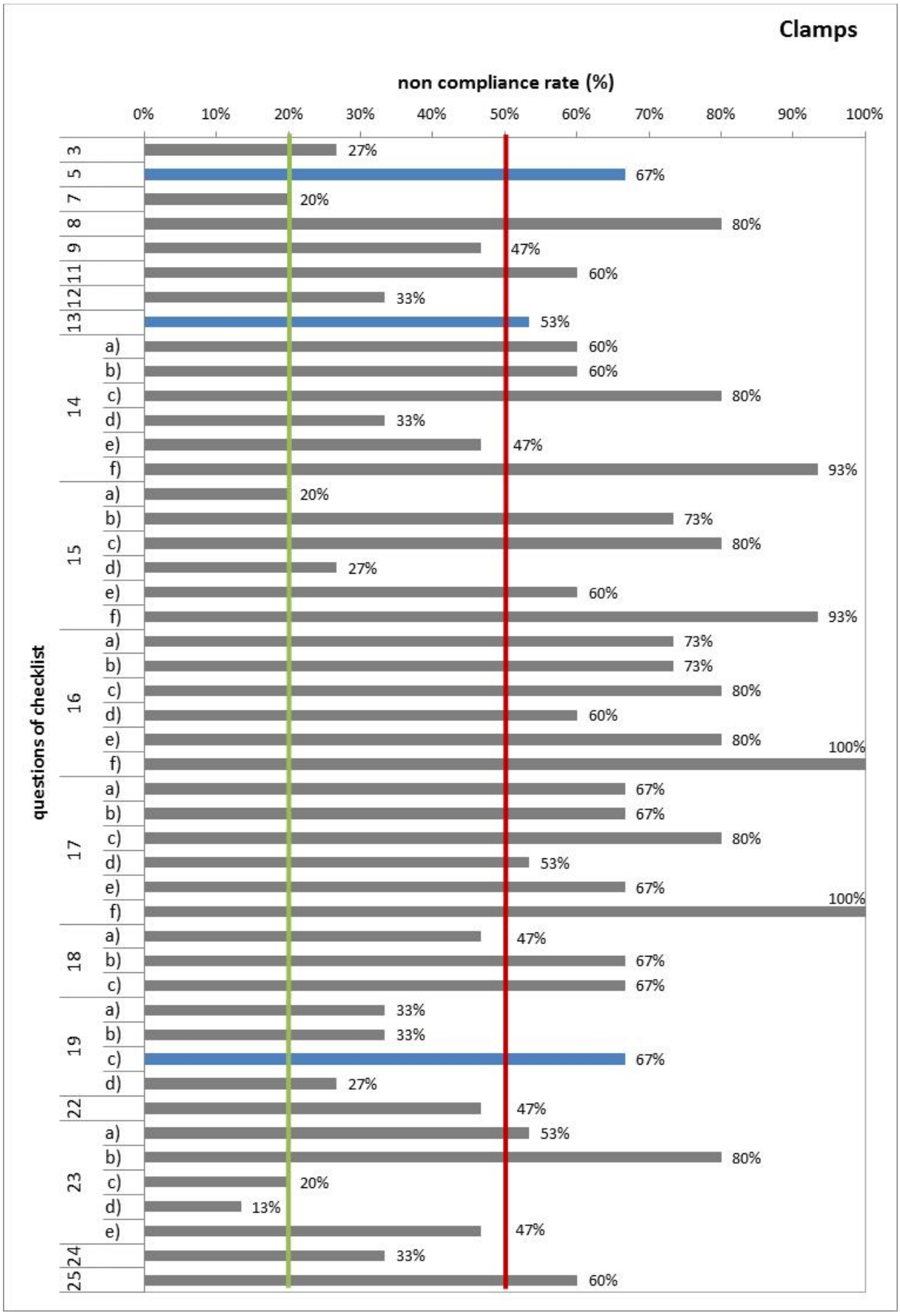

Fig. 8: *Non-compliant information provided in the IFU of clamps.*
Bars in blue = significant difference to other medical devices types.

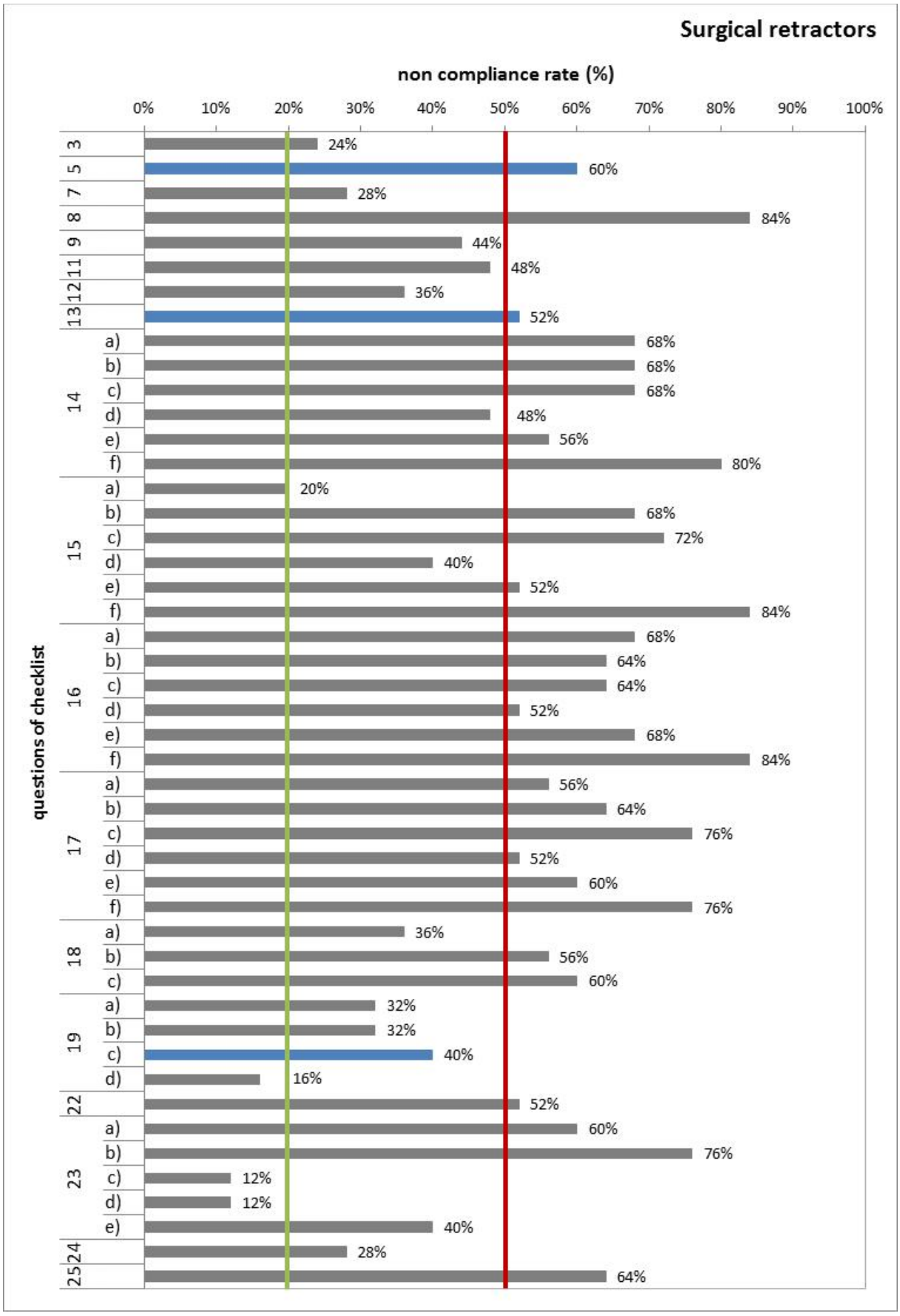

Fig. 9: *Non-compliant information provided in the IFU of surgical retractors. Bars in blue = significant difference to other medical devices types.*

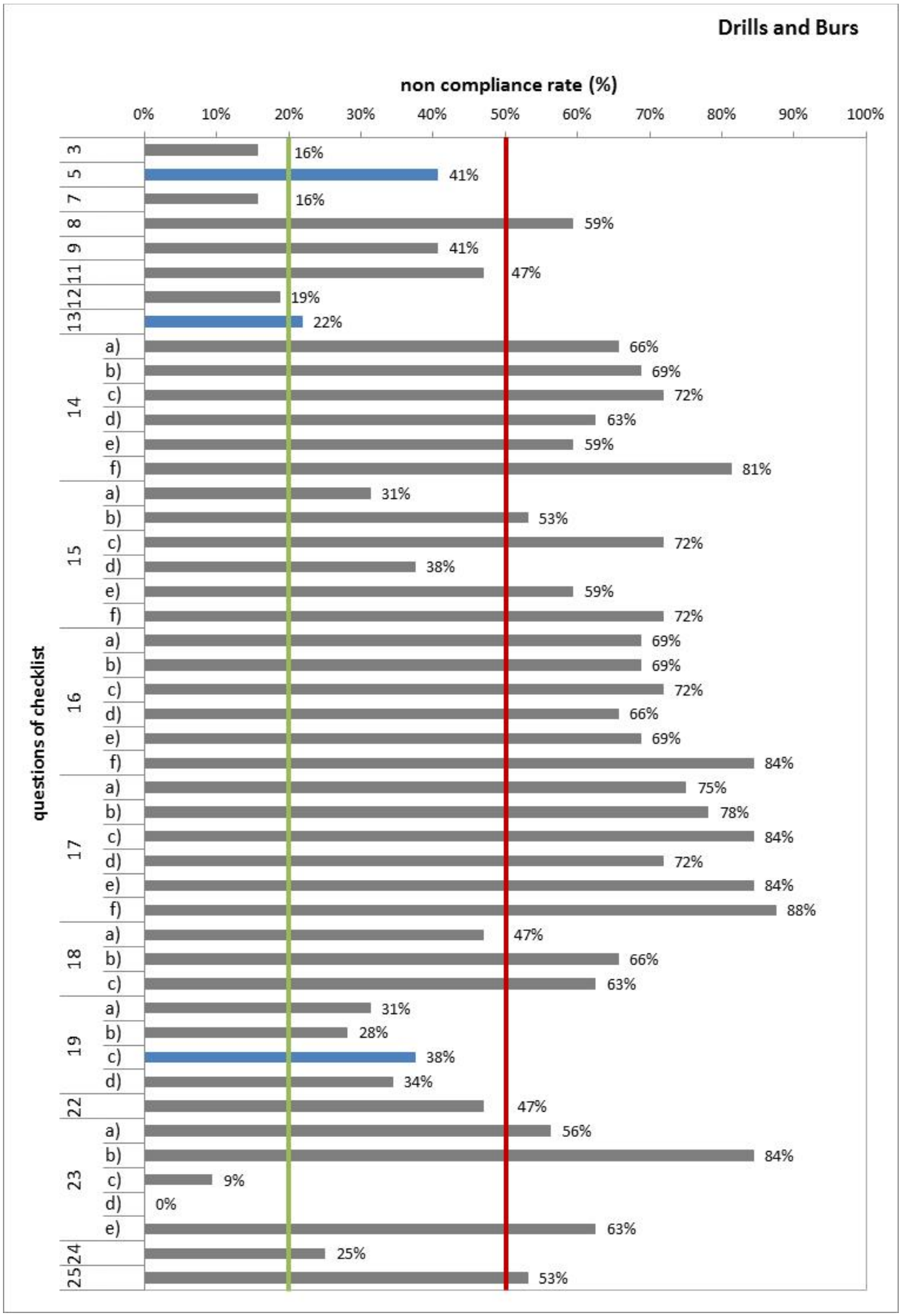

Fig. 10: *Non-compliant information provided in the IFU of drills and burs. Bars in blue = significant difference to other medical devices types.*

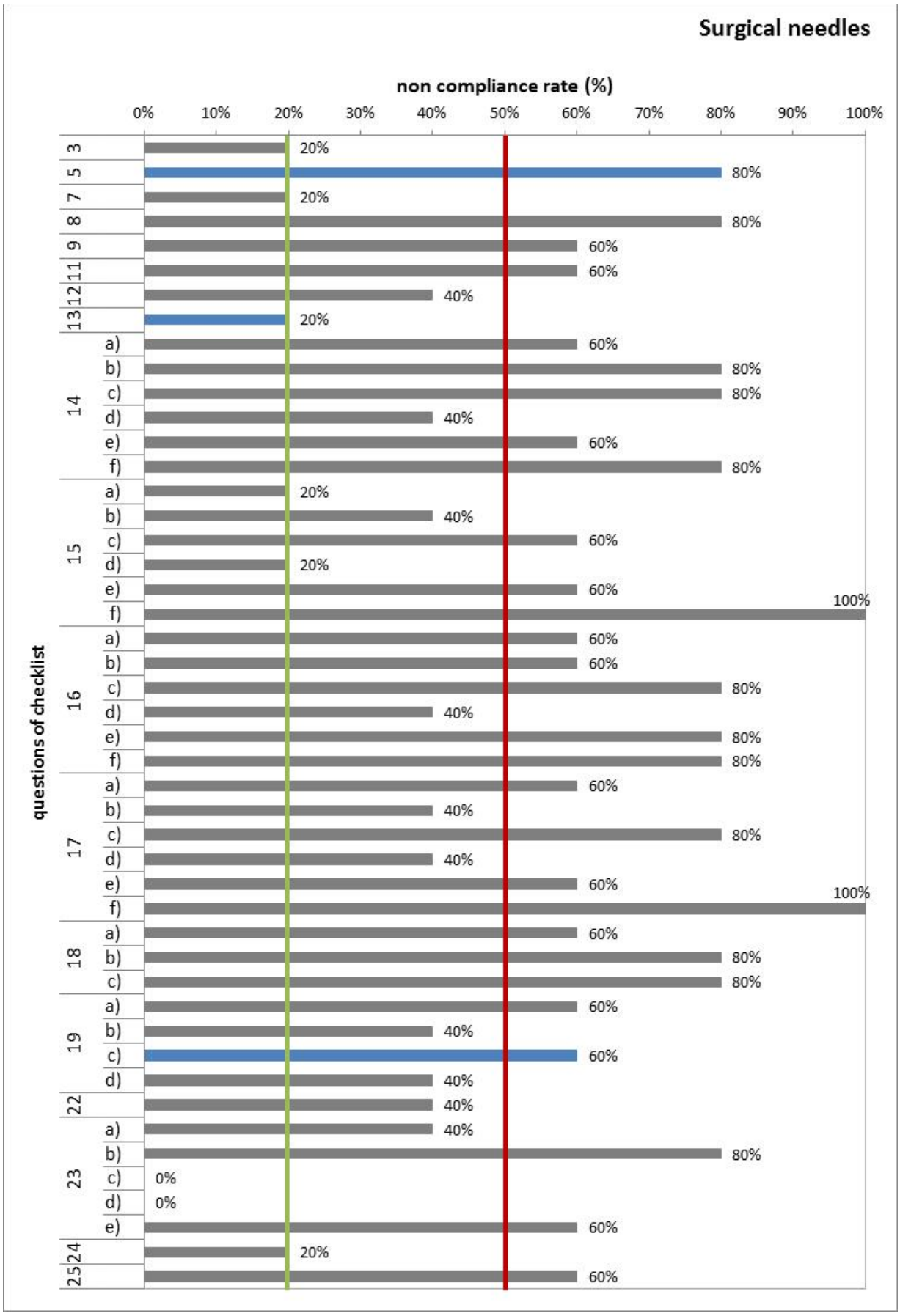

Fig. 11: *Non-compliant information provided in the IFU of surgical needles. Bars in blue = significant difference to other medical devices types.*

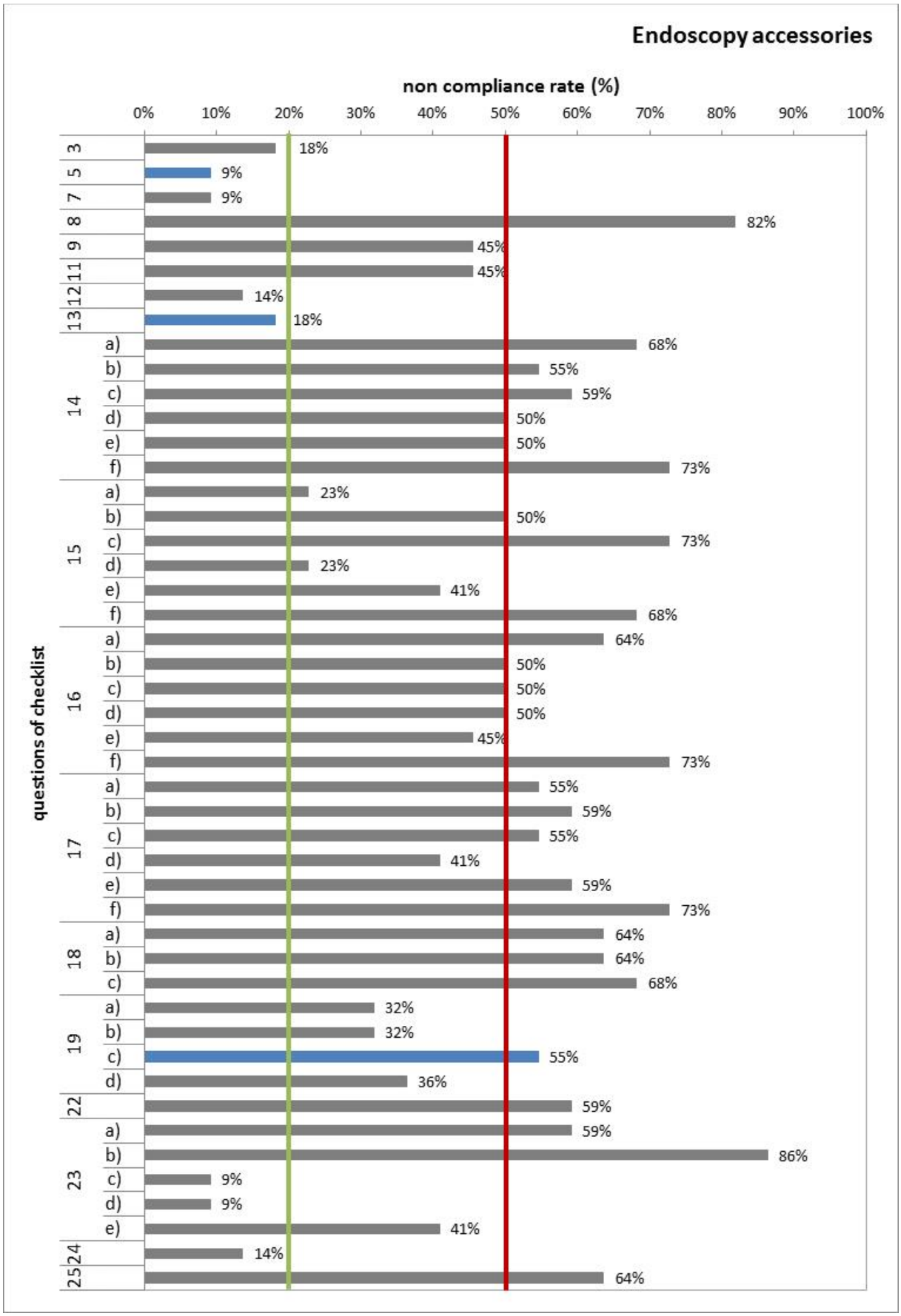

Fig. 12: *Non-compliant information provided in the IFU of endoscopy accessories. Bars in blue = significant difference to other medical devices types.*

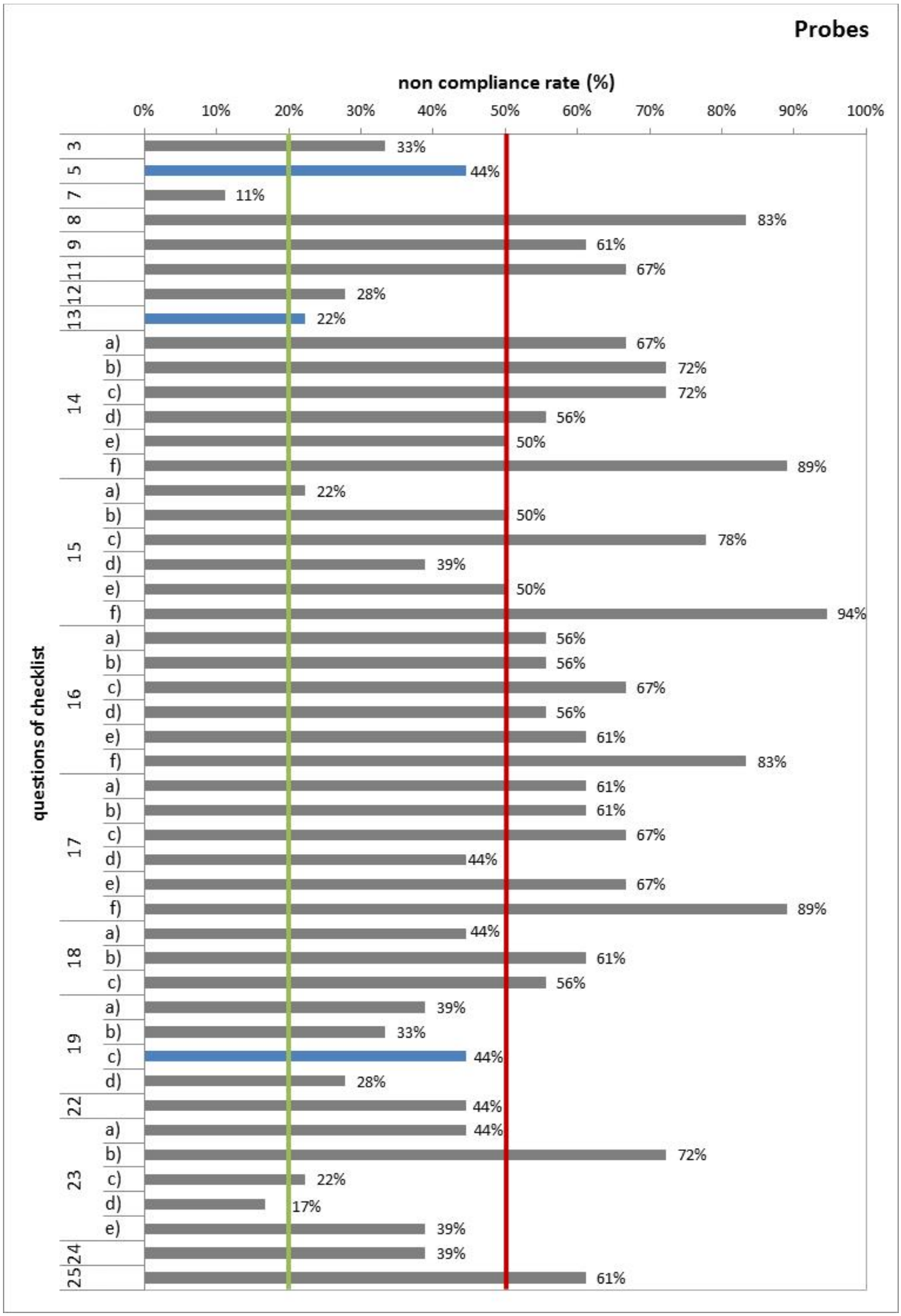

Fig. 13: *Non-compliant information provided in the IFU of probes.*
Bars in blue = significant difference to other medical devices types.

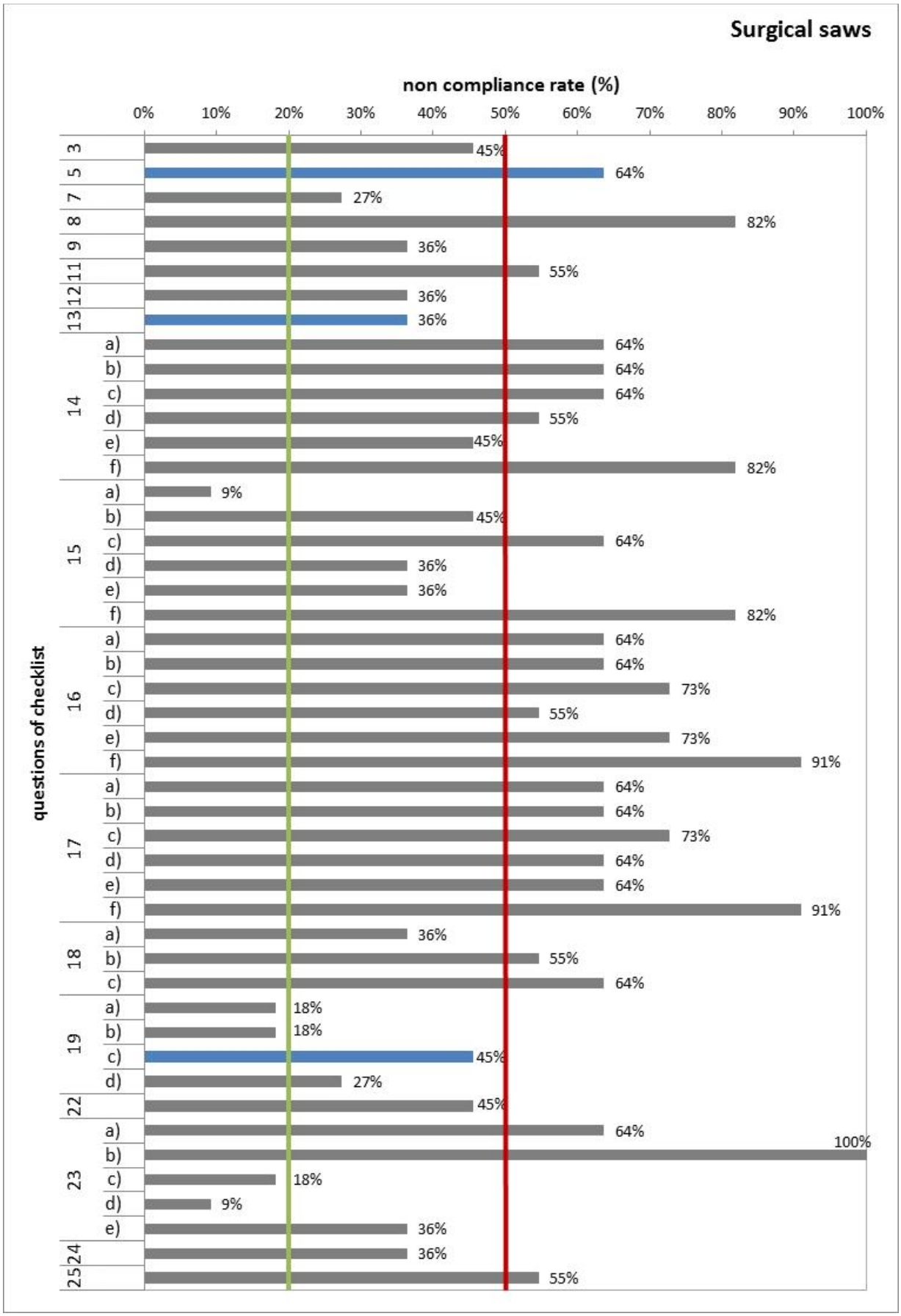

Fig. 14: *Non-compliant information provided in the IFU of surgical saws. Bars in blue = significant difference to other medical devices types.*

Comparison of risk classes

Table 7 shows the number of received checklists aggregated by risk class. The majority of medical devices assessed in this evaluation of compliance is risk class I (83,1%).

RISK CLASS	n
Class I	206
Higher than class I	42

Table 7: *Number of checklists presented by risk class*

Comparing the compliance rate of risk class I devices (Figure 15) with devices of risk classes higher than I (in the following called “other risk classes”; Figure 16) 11 of 47 questions (23.4%) show a significant difference in total.

For 9 questions risk class I devices are significantly less compliant than devices of other risk classes. For 2 questions risk class I devices are significantly more compliant than devices of other risk classes (Figure 17).

Risk class I devices show a significant/highly significant level of non-compliance for: Question 3 (Date of release stated on currently valid instructions for use) (p=0.01), 5 (Reusable device listed by catalogue number or reference number and device description available) (p= 0.00003), 8 (Limitations on reprocessing: Permitted number of reprocessing cycles) (p=0.002), 9 (End of life: Imperative conditions for not continuing to use the medical device) (p=0.006), 12 (Instructions provided in case preparation prior to cleaning is necessary) (p=0.04), 13 (Instructions for disassembly/re-assembly of the medical device) (p=0.01), 14f) (Automated cleaning: Limits and monitoring of chemical residues on the device) (p=0.02), 16e) (Automated disinfection: Process temperature + exposure time) (p=0.003) and 16f) (Automated disinfection: Limits and monitoring of chemical residues on the device) (p=0,00005).

Risk class I devices show a significantly higher compliance for question 15 a) (equipment to be used for manual cleaning) (p=0.03) and 23 e) (required pressure for sterilisation) (p=0.03).

When analysing in which aspects the non-compliance rate is equal to or higher than 50% of a certain risk class, it can be seen that this is the case for 33 questions for risk class I. Since for other risk classes this is the case for 32 questions, there is almost no difference between risk class I and other risk classes.

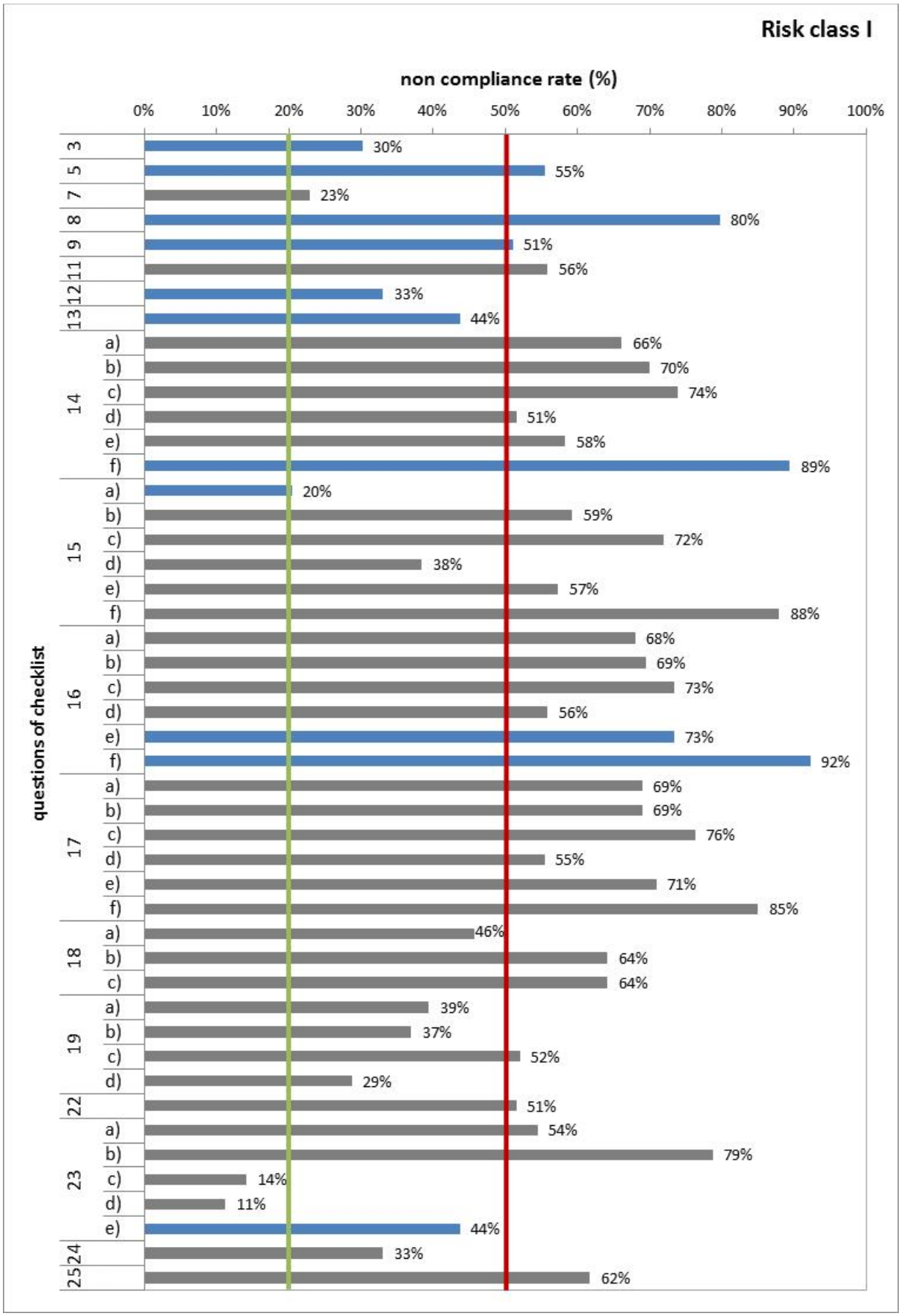

Fig. 15: *Non-compliant information provided in the IFU of risk class I medical devices. Bars in blue = significant difference to medical devices of other risk classes.*

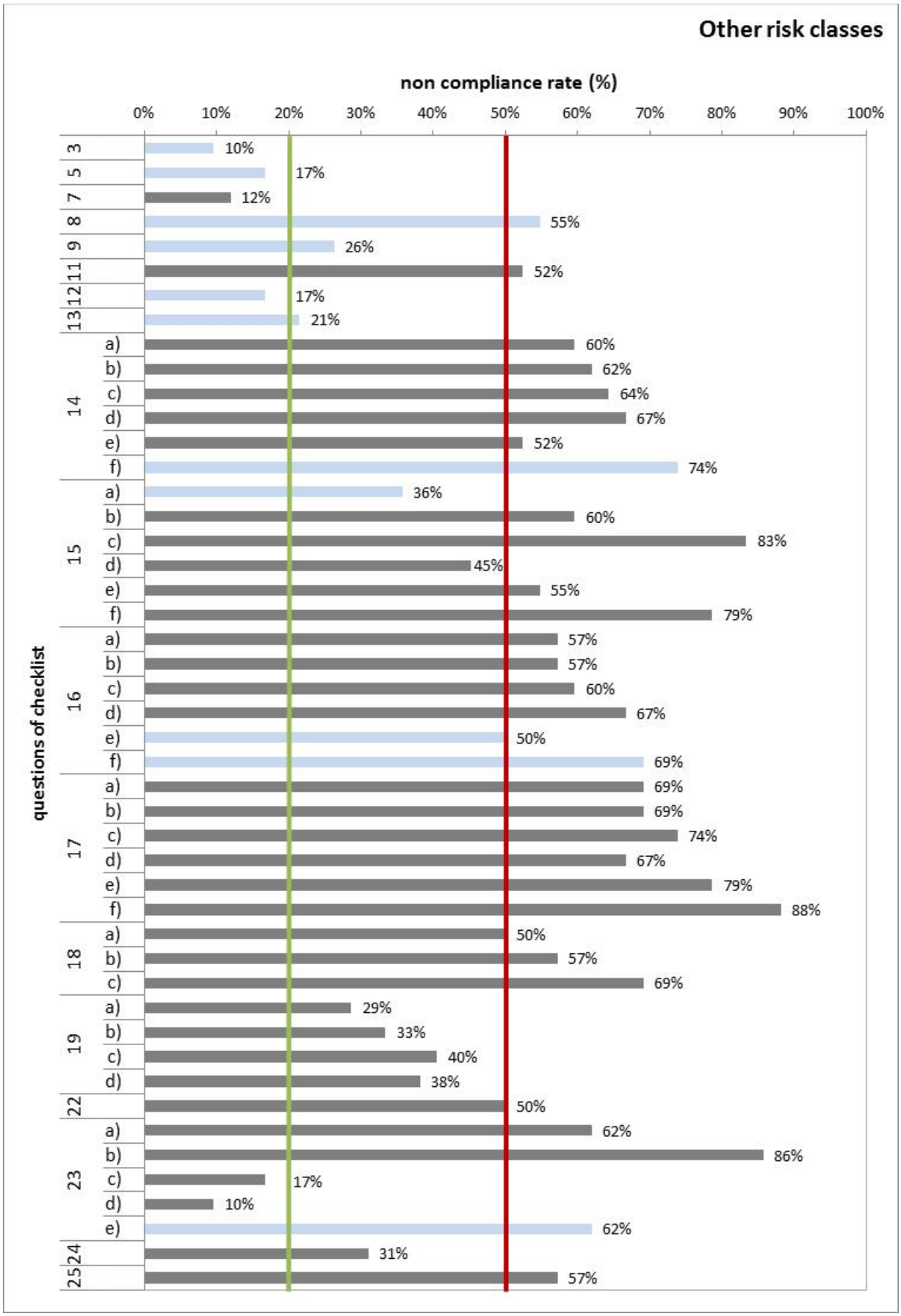

Fig. 16: *Non-compliant information provided in the IFU of medical devices of other risk classes. Bars in blue = significant difference to risk class I medical devices.*

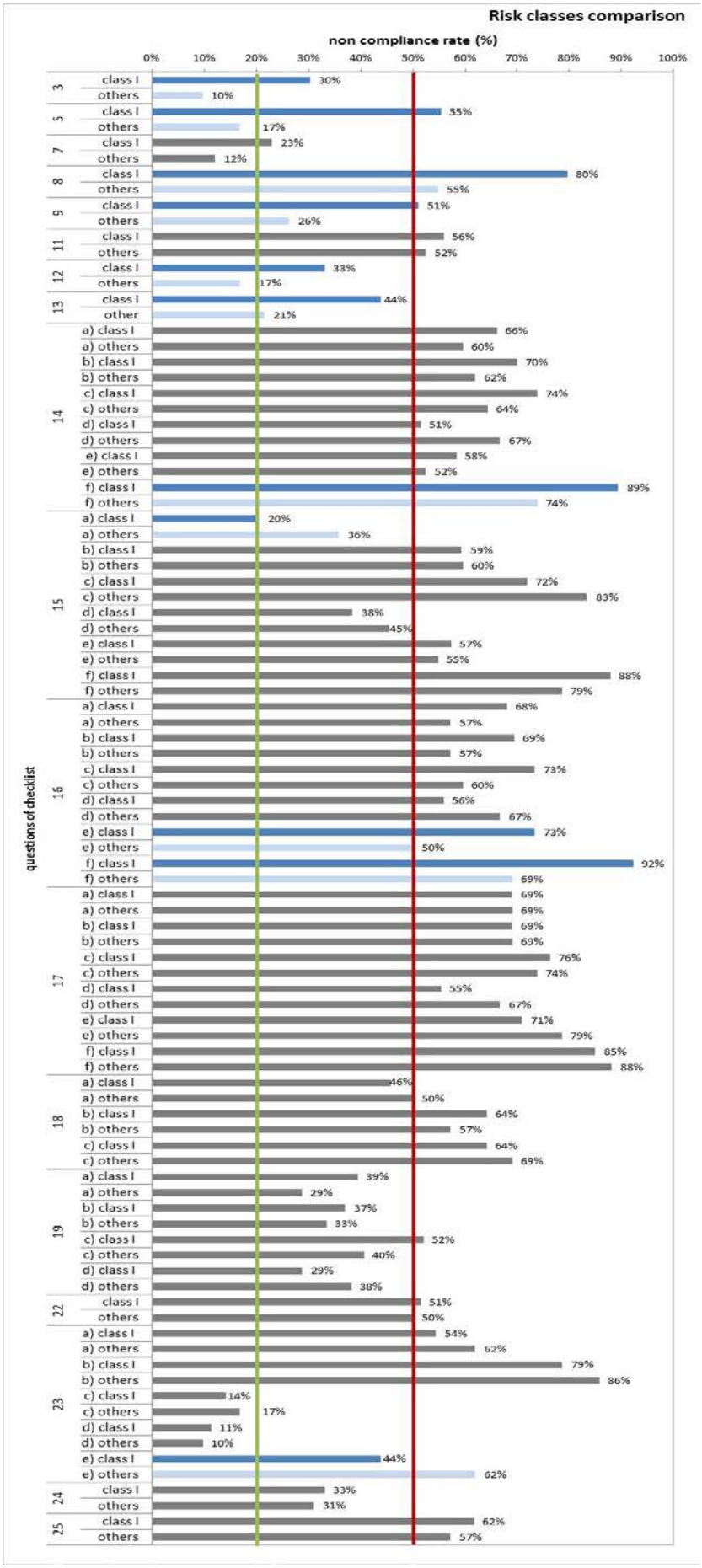

Fig. 17: *Comparison of medical devices of class I and of other risk classes. Bars in blue = significant difference between medical devices of class I and of other risk classes*

Legend for Fig. 15 to Fig. 17

Number of question and its content:

3 Instructions for use: Date of release stated on currently valid instructions for use
5 Device: Listed by catalogue number or reference number and device description available
8 Limitations on reprocessing: Permitted number of reprocessing cycles
9 End of life: Imperative conditions for not continuing to use the medical device
12 Preparation for cleaning: Instructions provided in case preparation prior to cleaning is necessary
13 Instructions for disassembly/re-assembly of the medical device
14 f) Cleaning: Automated – Limits and monitoring of chemical residues on the device
15 a) Cleaning: Manual – Equipment to be used
16 e) Disinfection: Automated – Process temperature + exposure time
16 f) Disinfection: Automated – Limits and monitoring of chemical residues on the device
23 e) Sterilisation – Required pressure

Comparison of company sizes

Comparing the compliance rate of small, medium and large companies, only 3 of 47 questions (6.4%) show a significant difference in total. Small companies (p=0.02) and medium companies (p=0.03) show a significantly higher compliance for question 3 (date of release stated on currently valid instructions for use) than large companies. Small companies show a significantly lower compliance for questions 14c) (automated cleaning: concentration of chemicals) (p=0,01) and 15e) (manual cleaning: process temperature + exposure time) (p=0,002) than large companies. No significant difference can be seen between small and medium companies (Figure 18-20).

An additional observation was made regarding the differences in total numbers of questions with a non-compliance rate of equal to or higher than 50%. While this is the case for 20 questions in large companies, small and medium companies show it for 32 questions. Overall, large companies show a non-compliance rate higher than 50% less often than small and medium sized companies.

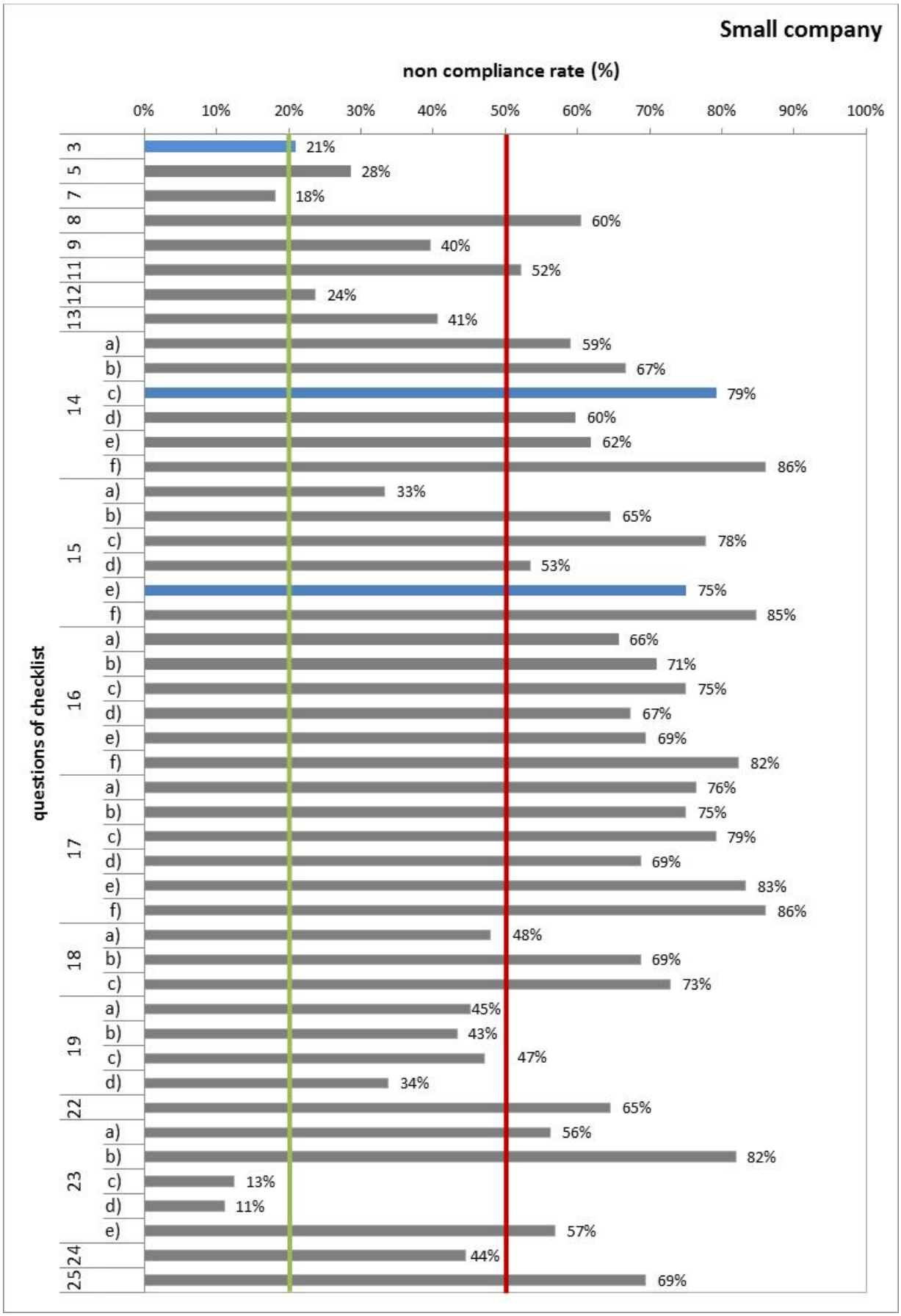

Fig. 18: *Non-compliant information provided in the IFU by small companies (n=72). Bars in blue = significant difference to other company sizes.*

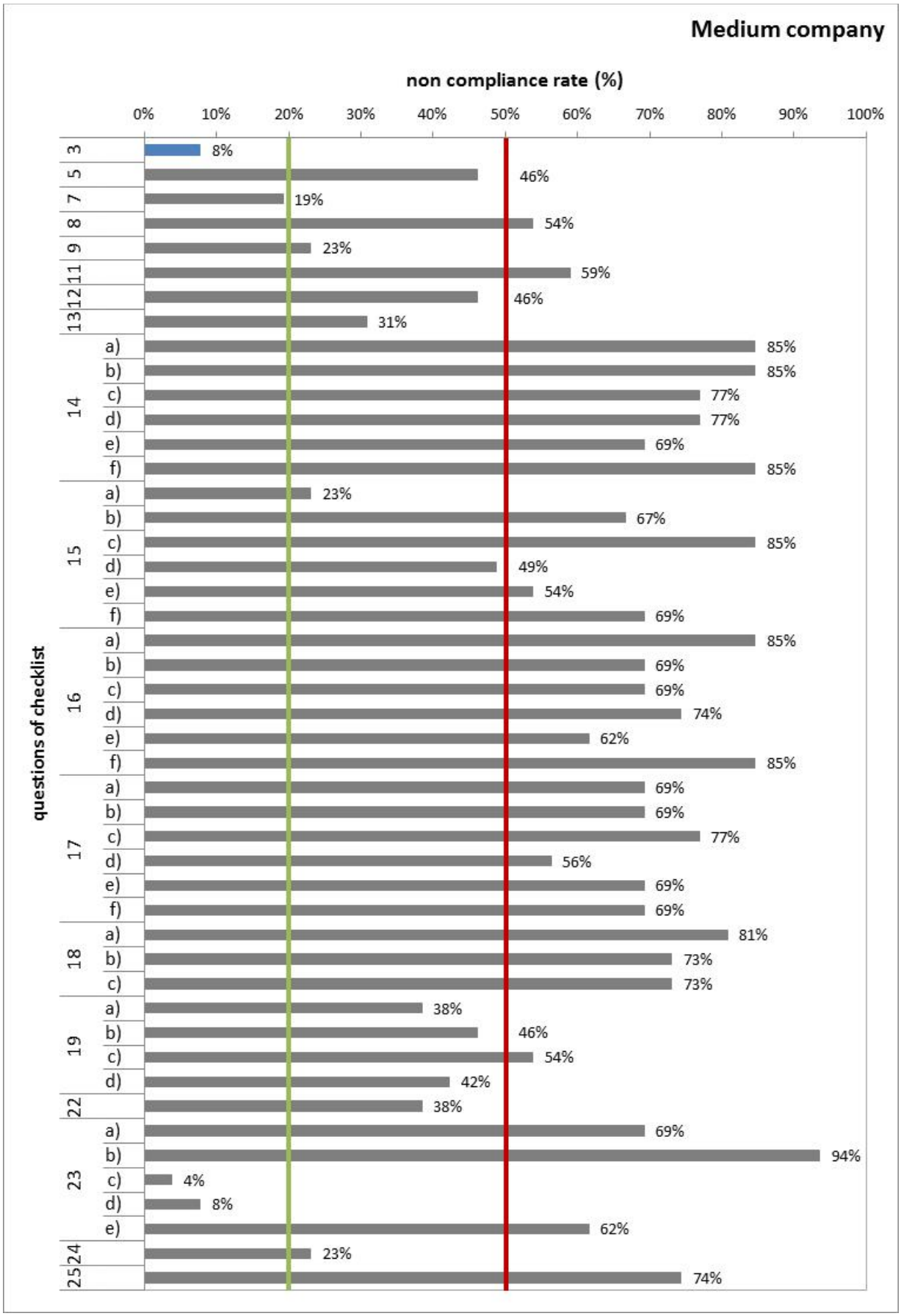

Fig. 19: *Non-compliant information provided in the IFU by medium companies (n=13). Bars in blue = significant difference to other company sizes.*

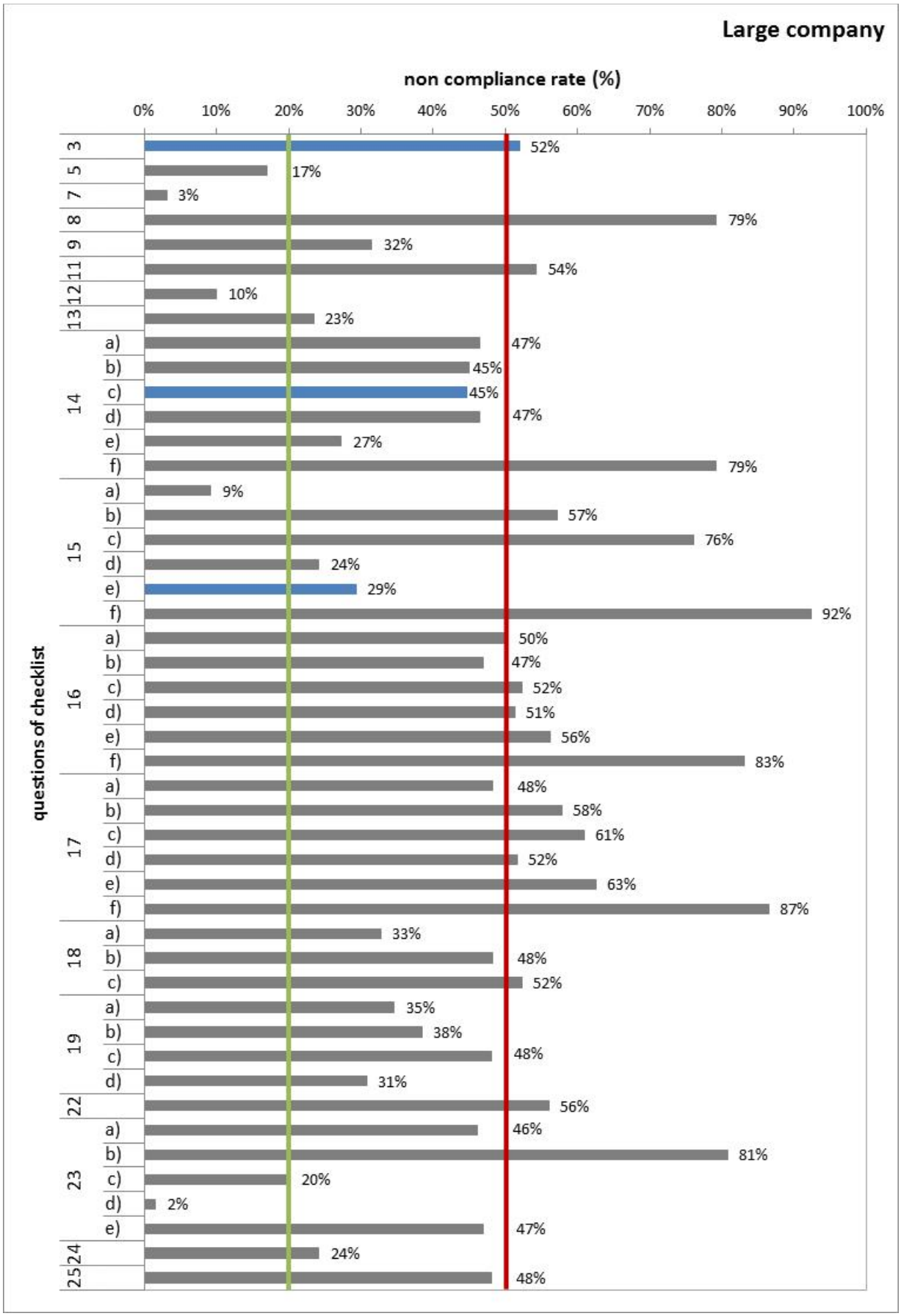

Fig. 20: *Non-compliant information provided in the IFU by large companies (n=13). Bars in blue = significant difference to other company sizes.*

Legend for Fig. 18 to Fig. 20
3 Instructions for use: Date of release stated on currently valid instructions for use
14c) Cleaning: Automated – Concentration of chemicals
15e) Cleaning: Manual – Process temperature + exposure time

DISCUSSION

I. Identification of appropriate economic operators and the corresponding reusable medical devices

Assembling the data from national databases, differences in quality and quantity of the data became evident. Some member states have a clear overview of what kind of economic operators (manufacturer, authorised representative, distributor) and medical devices are on their market whereas other member states can only provide families or groups of medical devices. This leads to a degree of uncertainty in determining the correct number of economic operators. It's possible that economic operators were not identified or that economic operators were originally listed although they do not meet the selection criteria.

The sample size was not selected to enable a complete assessment of product safety of re-processable medical devices, but to provide an overview of compliance in the market.

The majority of responses were related to class I medical devices as expected based on the classification criteria applied to re-usable surgical instruments.

II. Checking the compliance of the manufacturers' re-processing instructions

248 checklists from 98 economic operators were evaluated. Two third of the analysed questions (66,0%) show a non-compliance rate of 50% and higher. It is important to note not only the number of topics on which inadequate information was provided but their criticality. Where no adequate information on key steps is provided no safe and effective re-processing is possible. Our results therefore cast severe doubts on the validation quality of the manufacturers' re-processing procedures.

Only three questions - *warnings against points of particular attention*, *required temperature* and *minimum holding time of the steam during sterilization* - show a compliance rate higher than 80%. The high compliance rate of warnings regarding inappropriate chemicals and points of particular attention can be explained by the fact of legal considerations (e.g. warranty) by the manufacturer. The high compliance rate of temperature and minimum holding time of the steam was expected since the

germ-killing effect of damp heat and its application in the sterilization process is well documented and copious literature is available [11].

No clear trends were observed based on the type of medical device but overall compliance is correlated with the company size. Large companies showed a non-compliance rate of 50% and higher in 20 questions compared to 32 questions for medium and small companies. This might be due to higher number of products and therefore more interaction with audits of all kinds (e.g. notified bodies, supplier audits, Competent Authorities). It can also be assumed that large companies are in possession of more extensive regulatory and quality departments than small and medium sized companies. Thus more manpower is available for the same legal requirements.

The results also show that the non-compliance rate of information for re-processing depends to some extent on the risk class of the device. In general when observed a significant difference between risk class I and other risk classes, the re-processing instructions of risk class I devices tend to be less compliant. This might be due to the fact that risk class I devices can be placed on the market under the sole responsibility of the manufacturers, and without the consultation of a notified body, whereas the involvement of a notified body is compulsory for devices of higher risk classes. This outcome therefore strongly supports the changes included within the Medical Devices Regulations, recently adopted by the European Parliament, which will require that reusable surgical instruments falling within class 1 should also undergo a notified body review to further ensure that aspects relating to reprocessing are acceptably safe and in conformity with the Regulation.

Notwithstanding these observations, this exercise also highlights a need for significant improvement in the IFUs of devices which have in fact undergone assessment by a notified body by virtue of their higher classification. When using a different metric, such as a comparison of the number of questions with a non-compliance rate of 50% or more, it can be seen that there is almost no difference between risk class I (33 questions) and the other risk classes (32 questions). It is therefore recommended that the report of this Joint Action should be proactively shared and communicated with Notified Bodies and manufacturers of surgical instruments in anticipation of the new requirements.

SUMMARY

The documentation from the assessment of the re-processing instructions provided by the manufacturers show that the overall quality of this information is insufficient regarding compliance to the MDD 93/42/EEC.

No clear trends were observed based on the type of medical device but it was shown that overall compliance is correlated with the company size.

In general when observed a significant difference between risk class I and other risk classes, the re-processing instructions of risk class I devices tend to be less compliant. Notwithstanding these observations, this exercise also highlights a need for significant improvement in the instructions for use of devices which have undergone assessment by a notified body. It is therefore recommended that the report of this Joint Action should be proactively shared and communicated with Notified Bodies and manufacturers of surgical instruments in anticipation of the new legal requirements (Medical Devices Regulation).

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