



Voting Results

Ballot Information

Ballot reference	FprEN 17169
Ballot type	FV (Formal Vote)
English title	Tattooing - Safe and hygienic practice
French title	Tatouage - Bonnes pratiques d'hygiène et de salubrité
German title	Tätowieren - Sichere und hygienische Praxis
Work item Id	60065
Work item number	00435001
Procedure iteration	2
Vienna agreement status	None
Committee reference	CEN/TC 435
Committee secretariat	Germany (DIN)
Opening date	2019-07-11
Initial closing date	2019-09-05
Closing date	2019-09-05
Note	

Result of voting

(National Members having abstained are not counted in this vote.)

Approved by National Members

National Members approving: 20

National Members disapproving: 0

Number of Members approving: 100.000 % (requirement ≥ 55 %)

Weighted percentage of Population approving: 100.000 % (requirement ≥ 65 %)

Votes by National Members						
Country	Member	Participation	Approval	Disapproval	Abstention	Vote on dates
Austria	ASI	Member, Inside EEA	X			Abstain
Belgium	NBN	Member, Inside EEA	X			Yes
Bulgaria	BDS	Member, Inside EEA	X			Yes
Croatia	HZN	Member, Inside EEA			X	Abstain
Cyprus	CYS	Member, Inside EEA			X	Yes
Czech Republic	UNMZ	Member, Inside EEA	X			Yes
Denmark	DS	Member, Inside EEA	X			Yes
Estonia	EVS	Member, Inside EEA			X	Abstain
Finland	SFS	Member, Inside EEA	X *			Yes
France	AFNOR	Member, Inside EEA	X			Yes
Germany	DIN	Secretariat, Inside EEA	X			Abstain
Greece	NQIS ELOT	Member, Inside EEA	X			Yes
Hungary	MSZT	Member, Inside EEA			X	Abstain
Iceland	IST	Member, Inside EEA			X	Yes
Ireland	NSAI	Member, Inside EEA	X			Yes
Italy	UNI	Member, Inside EEA	X *			Yes
Latvia	LVS	Member, Inside EEA			X	Yes

Votes by National Members						
Country	Member	Participation	Approval	Disapproval	Abstention	Vote on dates
Lithuania	LST	Member, Inside EEA	X			Yes
Luxembourg	ILNAS	Member, Inside EEA				
Malta	MCCAA	Member, Inside EEA	X			Yes
Netherlands	NEN	Member, Inside EEA	X			Yes
North Macedonia	ISRSM	Member, Outside EEA			X	Abstain
Norway	SN	Member, Inside EEA			X	Yes
Poland	PKN	Member, Inside EEA	X			Yes
Portugal	IPQ	Member, Inside EEA	X			Abstain
Romania	ASRO	Member, Inside EEA				
Serbia	ISS	Member, Outside EEA	X			Yes
Slovakia	UNMS SR	Member, Inside EEA			X	Abstain
Slovenia	SIST	Member, Inside EEA	X			Yes
Spain	UNE	Member, Inside EEA			X	Abstain
Sweden	SIS	Member, Inside EEA			X	Abstain
Switzerland	SNV	Member, Outside EEA	X			Yes
Turkey	TSE	Member, Outside EEA			X	Abstain
United Kingdom	BSI	Member, Inside EEA	X *			Yes
TOTALS			20	0	12	

(*) A comment file was submitted with this vote

Comments from Voters			
Country	Member	Participation	
Finland	SFS	Member, Inside EEA	FprEN 17169 SFS.doc
Italy	UNI	Member, Inside EEA	FprEN 17169 UNI.doc
United Kingdom	BSI	Member, Inside EEA	FprEN 17169 BSI.doc

Template for comments and secretariat observations

Date:2019-09-06

Document: FprEN 17169

Project:

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Observations of the secretariat
-001					<p>Whilst GB understands that comments on this FV are purely editorial, our experts have noticed some additional points which need consideration, but which may not qualify as editorial. If you think our comments are more technical and therefore you cannot make a change, please retain them for a future revision.</p> <p>If it's possible to let me know your view that would be appreciated piera.johnson@bsigroup.com</p>		
GB-002		6.3.1	Figure 1		"Paper towels" are single use but not high risk.	Move "paper towels" into the box "single use" to the left.	For consideration.
GB-003		6.3.3.3 Cleaning (last sections, relating to needle cartridges)	9 th paragraph		<p>'Where a needle cartridge is sealed to effectively prevent liquid transfer into the needle cartridge holder, such that there is no ingress of body fluids, the needle cartridge holder is not regarded as high-risk equipment'</p> <p>This paragraph currently introduces the concept of needle cartridge use somewhat 'out of the blue'</p> <p>There is insufficient explanation of needle cartridges, leading to confusion in those not already familiar with these systems.</p>	<p>For clarity and better phrasing, we suggest the following text amendment.</p> <p>Delete the paragraph and rewrite as follows: 'Some tattoo needle systems are designed where the needle is fixed in a single use cartridge, sealed such that body fluids cannot contaminate the cartridge holder in the tattoo machine. If this seal is effective, the needle cartridge holder is not regarded as high-risk equipment.'</p>	Significant
GB-004		6.3.3.5	1 st para		<p>"High-risk equipment according to Figure 1 shall be sterilized".</p> <p>There are two categories of high-risk equipment in Figure 1 – one to be disposed of and not sterilized & reused; the other that can be sterilized – termed "reusable".</p> <p>Referring to high-risk equipment in 6.3.3.5 as though there was only one category of high-risk equipment is confusing when there are two categories in Figure 1.</p>	<p>Amend text to read "High-risk <u>reusable</u> equipment according to Figure 1 shall be sterilized"</p>	Significant.
GB-005		6.3.3.5	4 th para		<p>"Where high risk equipment is to be reused and is sent offsite for disinfection and sterilization".</p> <p>Such equipment is not sent offsite for disinfection.</p>	<p>Change to "Where high risk equipment is to be reused and is sent offsite for sterilization"</p>	Significant

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)

2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

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						Delete 'disinfection'.	
FI- 006		7.8		te	<p>Requirements concerning labelling seem to be based mainly on the marking requirements of the Regulation (EC) No 1223/2009 on cosmetic products.</p> <p>However, tattoo inks belong under the scope of chemical legislation, so the labelling should be based to CLP and REACH instead. Chemical legislation does not have requirements regarding shelf life, guarantee of sterility or naming of all substances, but it does have requirements about adding warnings to the labels and, in the future, naming of certain allergens (if included in the ink).</p> <p>Further information about this is available at: https://echa.europa.eu/documents/10162/0/restrictions_axvrep_tattoo_inks_sps-012420-16_en.pdf/f8c09d52-1f42-9b9c-4a54-90e8c843d205</p>		
NC IT- 007	26-27- 28	7.9		te	<p>I propose to remove the comma highlighted in red and to add "steril" because the disposable spatula are not suitable for that type of use. It is known that non-sterile spatulas are used for other uses. Steril spatulas are easily available on the market at very low costs.</p>	<p>I propose to change the paragraph:</p> <p>"apply and remove surplus lubricant with a single use spatula or a spatula, which is capable of being sterilized and is sterilized between clients. Note the date of opening on the jar. The maximum period of use after opening is six months;"</p> <p>into:</p>	

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						“apply and remove surplus lubricant with a single use type A sterile woodem spatula or a spatula which is capable of being sterilized and is sterilized between clients. Note the date of opening on the jar. The maximum period of use after opening is six months;”	
GB- 008		Bibliography			<p>The following in the bibliography have so little relevance to this standard that they should not be included:</p> <p>EN ISO 1271 – Tattooists would not use surgical hand disinfection. (EN 1500 for hygienic handrubs is in the normative references)</p> <p>EN ISO 11810 The resistance of surgical drapes to lasers has no relevance</p> <p>IEC 82079 has insufficient relevance. We are not expecting tattooists or anyone associated with them to write instructions to that level of standard.</p>	Delete these from the bibliography	For consideration.

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