CLAIM OF DEFECTIVE HYGIENE PROCEDURE ON EUROPEAN STANDARD				
Reference	**Claim issued by :**		**Issued to :**	**Date**
CLAIM 2 2017/V01	**SNCLD**	**ANNEX I**	Mrs. **Elena SANTIAGO CID** Director General - CN/CCMC	2017/04/05

I. Defective hygiene procedures: wax depilation

Unless it gives obligation to proceed to wax depilation only with single use products and instruments, publication of EN 16708 would lower usual safety requirements; lower safety practices; give a false impression of safety to customers, and challenge public confidence to the industry.

1. Considering the standard covers wax depilation;
2. Considering wax depilation may significantly expose service provider and customers to accidental contact with blood and bodily fluids;
3. Considering wax depilation exposes service provider and customers to contacts with biological agents as staphylococcus, enterococcus and faecal germs, including virus, fungus and drug resistant germs as MRSA and VRSA staphylococcus, ESBL, VRE enterococcus and MRAB;
4. Considering the standard specifically recommends “wax heater" for “wax depilation”[1];
5. Considering wax depilation with warm wax exposes to cross contamination by biological agents and accidental but frequent penetration in the skin of harmful and possibly lethal biological agents as hepatitis virus;
6. Considering the standard gives choice between “use of single use applicators or use of separate containers”[2];
7. Considering use of “separate containers” is not an equivalent protection to “single use” container, because it allows usage of “reusable wax” in “reusable containers”, exposing to cross contamination and penetration in the skin of harmful biological agents including lethal biological agents;
8. Considering there is consensus among hygienists and serious industry to forbid usage of “reusable wax” and/or “reusable containers” to limit cross contamination during professional wax depilation;
9. Considering the standard covers “wax resin roller applicators”[3];
10. Considering usage of “wax resin roller applicators” exposes to cross contamination and penetration in the skin of skin with harmful biological agents including lethal biological agents;
11. Considering the standard recommends unspecified “suitable disinfection (…) in accordance with the manufacturer’s instructions” for wax resin roller applicators;
12. Considering unspecified “manufacturers” are no obligation to deliver guidance for professional disinfection;
13. Considering “wax resin roller applicators” may be accidentally - but often - put in contact with small quantities of blood and bodily fluids issued from extracted hair follicular units;
14. Considering that, on such a case, only disinfection covered by appropriate European standards[4] in similar circumstances might be appropriate;

[1] Annex A Table A.1
[2] § 4 clause 5.11.1
[3] § 5 clause 5.11.1
[4] EN 1040, 1275, 1499, 1500 (basis), and EN 12353, 12791, 13561, 13562, 13563, 13624, 14347, 14348, 14476, 14652, 14561, 14562, 14563, 14885 (quantitative)

15. Considering that in hospitals the use of disinfection after contact with blood and bodily fluids is strictly limited to the cases when it is impossible to use sterilization or single use instruments;
16. Considering there is no disinfection, as defined by European standards, able to eliminate harmful biological agents including lethal biological agents as released by wax depilation;
17. Considering single use instruments and products for wax depilation would have only minor impact on the the price of the procedure, would not limit access to the public to professional depilation, and would not limit expansion of such a commerce;
18. Considering the standard has no normative obligations for usage of single use wax and spatulas for depilation;
19. Considering, as a result, the standard has no normative obligation to prevent service provider and facility from contamination with blood and internal bodily fluids *during* wax depilation procedure;
20. Considering the standard has no normative obligation to prevent service provider and facility from cross contamination with internal bodily fluids and blood *after* wax depilation procedure;
21. Considering the standard has no normative obligation for disinfection of hands and surface complying with existing disinfection's European standards *after* wax depilation procedure;
22. Considering "state of the art" safety requirements in the beauty salon services industry includes single use wax and spatulas, no usage of rollers, usage of single use gloves, standardized disinfection procedures and standardized elimination of sceptic waste;
23. Considering majority of service providers in beauty salon services industry complies with those "state of the art" requirements;
24. Considering the standard requirements for wax depilation are lower than "state of the art";

We require CEN to withdraw this standard until hygiene requirements of section I are met.

II. Defective hygiene procedures: physically invasive procedures

Unless it includes appropriate normative qualification requirements publication of EN 16708 covering physically invasive procedures would lower safety requirements, lower safety practices and expose customers to lethal risks

25. Considering physically invasive procedures are defined as procedures overtaking the natural barrier of stratum corneum and penetrating in living parts of the skin[5];
26. Considering overtaking the natural barrier of stratum corneum and penetrating in living parts of the skin creates a risk of contact with blood and internal bodily fluids;
27. Considering penetration in the skin of biological agents is harmful and may expose to lethal risks;
28. Considering for public safety any professional contact with internal bodily fluids and blood in living parts of the skin must be sterile;
29. Considering invasive procedures have to prevent any cross contamination between service provider, customers and facilities by blood and/or bodily fluids, before, during and after the procedure;
30. Considering the standard covers electrical epilation (electrolysis), chemical peels, intra-dermal pigmentation (micropigmentation), micro-needling (roller needling) and mesotherapy;
31. Considering those five procedures are physically invasive procedures;
32. Considering physically invasive procedures have to be delivered only when risk management conditions are applied and by specially trained professionals;
33. Considering even single use wax depilation with single use instruments and standardizes disinfection requirements requires to « take responsibility for completion of tasks" as defined by EQF 3;

[5] or sterile cavities of the body (out of the scope)

34. Considering the wording “can include” before a training requirement means that the requirement is not compulsory.
35. Considering the wording “can include” is used before EQF 3, EQF 3 is not the minimal training requirement, even for wax depilation.
36. Considering when authorized to non-medical practitioners, physically invasive procedures - except for wax depilation- requires EQF 6 qualification or EQF 5 plus a very specific training and additional risk management procedures;
37. Considering except for intra-dermal pigmentation, EN 16708 has no EQF normative requirements for physically invasive procedures[6],[7].

We require CEN to withdraw this standard until training requirements of section II are met.

III. Defective hygiene procedures: external exposure with blood and other bodily fluids

Unless it includes necessary normative obligations, publication of EN 16708 covering procedures with exposure to external contact with blood and other bodily fluids would lower safety requirements, lower safety practices, be a threat to public health and expose vulnerable service providers and customers to lethal risks.

38. Considering the standard includes five “invasive procedures” with exposure of *external layers* of skin to blood and/or bodily fluids and other non-invasive procedures as wax depilation that may accidentally but frequently expose to blood and/or bodily fluids;
39. Considering the standard uses the wording “should” and not “shall” when considering “the risk of contact infection” following exposure to “blood contact and other bodily fluids"[8];
40. Considering the use of “should” means there is no normative obligation when considering “the risk of contact infection” following exposure to “blood contact and other bodily fluids";
41. Considering such an exposure will disseminates drug resistant germs and may contaminate sub consequently service providers and customers with potentially lethal biological agents;
42. Considering such a contamination exposes *vulnerable* people to lethal risks,
43. Considering dissemination of drug resistant germs contributes to endanger population;
44. Considering only single use instruments must be used in case of risk of potential of exposure to blood and/or bodily fluids;
45. Considering disinfection of surfaces, hands and devices exposed to blood and/or bodily fluids must include normative obligation to comply with appropriate European standards[9];
46. Considering when such an exposure is concerned, the standard has no normative requirements complying with any European standards for disinfection of surfaces, hands or devices (ibid.);
47. Considering disinfection after “contact with blood or other bodily fluids” cannot been achieved in a beauty salon by employee’s without minimal qualification of EQF 3;
48. Considering there is no normative obligation of such EQF 3 qualification (see clause 34 & 35);
49. Considering disinfection after “contact with blood or other bodily fluids” cannot be achieved in “mobile services”[10],[11] including client’s home, camping, festivals, and any outdoor locations;

[6] “can include” is not a normative requirement (clause 3.1 in example 2)
[7] Annex A is “informative”
[8] § 1 clause 5.7 (use of “should”)
[9] to be selected within European standards as EN 1040, 1275, 1499, 1500 (basis), and EN 12353, 12791, 13561, 13562, 13563, 13624, 14347, 14348, 14476, 14652, 14561, 14562, 14563, 14885 (quantitative)
[10] As defined in clause 2.9

50. Considering safety alert issued by World Health Organization in April 2014 on drug resistant bacteria being a “major threat to public health”;
51. Considering the m service providers are very aware of the risks and and cautious with risk management when external exposure with blood or bodily fluids is concerned;

We require CEN to withdraw this standard until hygiene requirements of section III are met.

IV. Defective hygiene procedures: use of “reusable instruments that has the potential to be abrasive or pierce the skin”

Publication of EN 16708 as it is, authorising reusable instruments for invasive procedures, is in contradiction to any known standards and would expose service providers and customers to lethal risks.

52. Considering the standard specifically authorises "*reusable* instrument that has the potential to be abrasive or pierce the skin"[12];
53. Considering such procedures are “physically invasive” procedures;
54. Considering if they have potential to *pierce* the skin, usage of reusable instruments may transmit drug resistant germs and lethal virus and biological agents potentially lethal for vulnerable people;
55. Ç)cConsidering even in hospitals, for diagnosis and therapeutic use, there is a consensus to strictly limit usage of reusable instruments and devices to the only situations where no alternative exists;
56. Considering for cosmetic use, there is never a necessity to deliver a procedure;
57. Considering for cosmetic use, there is always a safer alternative;
58. Considering cosmetic customers are often vulnerable[13];
59. Considering if use of instruments that have the potential to be abrasive or pierce the skin had to be considered for cosmetic purpose, only single use instruments must be used.

We require CEN to withdraw this standard until hygiene requirements of section IV are met.

V. Defective hygiene procedures: sterilization of reusable instruments contaminated with blood or bodily fluids

Publication of EN 16708 as it is deteriorates requirements for vital sterilization process. EN 16708 is in contradiction to any known sterilization standard and would expose service providers and customers to lethal risks.

Publication of EN 16708 as it is would be detrimental to the reputation of CEN by introducing doubts on quality and safety of CEN standards.

Publication of EN 16708 as it is, by introducing de facto a new standard of sterilization, would be detrimental to harmonization of ISO and CEN sterilization’s standards.

60. Considering the standard introduces a normative obligation of sterilization of “reusable instruments that could potentially become contaminated with bodily fluids”[14];

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[11] § 1 clause 1 : scope
[12] Note 1 clause 5.7
[13] Sir Bruce Keogh review
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192028/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf
[14] § 2 and 4 clause 5.7

61. Considering the standard normative obligation of sterilization is not specific: “The use of suitable chemical agents, or other suitable methods capable of killing bacteria and blood borne viruses such as hepatitis B and C and HIV, shall be used for sterilization [15]”;
62. Considering the expectations and outputs expected from such a sterilization process are critical, as long as “killing” bacteria, hepatitis and HIV virus is targeted;
63. Considering the only explicit method to comply with normative obligation of sterilization is “use of suitable chemical agents”;
64. Considering because of their high toxicity, the only efficient “chemical agents” by their own are only used in strictly controlled industrial dependencies and never used for sterilization by professionals;
65. Considering there is no “suitable chemical agent” to be used *alone* for sterilization by professionals as defined by established standards for sterilization as EN 665;
66. Considering the only “suitable method” for killing bacteria and blood borne viruses on contaminated instruments is sterilization, as defined by EN 665 or 13060;
67. Considering sterilization is defined as a process able (a) to eliminate nearly any form of biological agent ($\leq$ 1 per million) from a reusable device, (b) to maintain that state by sealing, (c) to maintain the effectiveness of the process by quality management system;
68. Considering the standard introduces a new method of sterilization which is supposed to be defined by manufacturers’ instructions “where chemicals agents are used the manufacturer's instructions shall be followed”[16];
69. Considering there is no “manufacturer’s instructions” for chemicals agents to be used *alone* for sterilization as defined by EN 665 or 13060;
70. Considering the standard suggests that “manufacturers of chemical agents used for sterilization have obligations under Directive 98/8/EC”;
71. Considering Directive 98/8/EC is abrogated since 1 September 2013 ;
72. Considering Directive 98/8/EC replaced by regulation (EU) No 528/2012, establishes a list of 798 substances which may be used on European market, 109 of them being on the category disinfectants or algaecides[17];
73. Considering regulation (EU) No 528/2012 ensures any biocidal product on the market “is sufficiently effective”, “has no immediate or delayed unacceptable effects”[18] or “is essential to prevent or control a serious danger to human health”[19];
74. Considering any sterilization process involves at least five specific stages : washing and drying process, use of a proper standardized sterilization program, sealing process and quality management process;
75. Considering regulation (EU) No 528/2012 does not deliver any insurance that biocide’s manufacturer has obligation to deliver guidance for such stages of sterilization process (or any process as defined by EN 665 or 13060);
76. Considering regulation (EU) No 528/2012 may deliver guidance for disinfection;
77. Considering disinfection is not a suitable process for sterilization of reusable instruments contaminated by blood or bodily fluids ;
78. Considering the standard suggests that “an autoclave shall be used products to sterilize suitable tools and instruments”[20];
79. Considering the use of “autoclave” is obsolete;

[15] § 4 clause 5.7
[16] § 4 clause 5.7
[17] Extraction the 13th of January 2016 from the database under UE n° 528/2012 establishing the list of substances which may be used on European market.
[18] Point (b) article 19 (1)
[19] Points (a), (b), (c) article 5(2)
[20] § 4 clause 5.7

80. Considering the use of an “autoclave” will never deliver *by itself* any sterilization process as defined by EN 665 or 13060;
81. Considering there is a consensus within hygienists to avoid sterilization outside of hospitals or specialized facilities, even in medical or dental facilities, when single use alternatives are available[21];
82. Considering sterilization, as defined in EN 665 or 13060, cannot been achieved in beauty salon’s facilities as described in the standard;
83. Considering sterilization, as defined in EN 665 or 13060, cannot been achieved by service providers with no minimal normative obligations of qualification (see clause 34 & 35);
84. Considering ratification of EN 16708 would create a new process allowing disinfection for contaminated reusable invasive instruments and authorising beauty salons to proceed to it and to use them;
85. Considering sterilization and disinfection are major concerns for public health;
86. Considering cross contamination by drug resistant bacteria’s is a major concerns for World Health Organization;
87. Considering standardization process of sterilization and disinfection for non-medical cosmetic purpose in beauty salon has not involved professionals of hygiene, sterilization and disinfection;
88. Considering standardization process of sterilization and disinfection for non-medical cosmetic purpose in beauty salon has not involved CEN/TC 204 and CEN/TC 216/WG1;
89. Considering standardisation of sterilization and disinfection for non-medical cosmetic purpose in beauty salon has not been approved as a new CEN/TC;
90. Considering there is an harmonization process between ISO and CEN standards about sterilization;
91. Considering TC/409 in charge of beauty salons has no minimal knowledge to enter in standardisation of sterilization or disinfection process;
92. Considering sterilization in beauty salons, by professionals with no minimal qualification, with unspecific “chemical agent” and by “autoclave” contradicts any recognized practice of sterilization, and contradicts the hygiene principle to avoid sterilization when single use is available;

We require CEN to withdraw this standard until it cancels any reference to sterilization process, and forbids usage of reusable instruments if possibly contaminated with blood or bodily fluids.

VI. Defective hygiene procedure: disinfection

93. Considering in EN standards[22] disinfection is able to eliminate from 1 per 10 000 to 1 per 100 000 biological agents;
94. Considering in EN 665 or 13060 sterilization is able to eliminate 1 per one million biological agents;
95. Considering in European standards disinfection delivers a temporary result for immediate use, when sterilization delivers a long lasting result by sealing;
96. Considering in European standards disinfection does not incorporate washing, drying, heating, sealing processes nor quality management process, when sterilization does;
97. Considering EN 16708 standard suggests that “where chemicals agents are used the manufacturer's instructions shall be followed”;
98. Considering there is no recognise method to eliminate by disinfection viruses as HIV 1, Rotavirus, Herpes virus, FCV, HAV, H1N1, H3N7, H5N1, HBV, HCV;
99. Considering manufacturer’s instructions may only provide instructions for surface or hand disinfection with a temporary result;
100. Considering disinfection is a imperious process to prevent spread of numerous harmful biological agents;

[21] It is even forbiden in countries like Switzerland

[22] EN 1040, 1275, 1499, 1500 (basis), and EN 12353, 12791, 13561, 13562, 13563, 13624, 14347, 14348, 14476, 14652, 14561, 14562, 14563, 14885 (quantitative)

101. Considering there is no normative obligation in EN 16708 for disinfection as defined by European standards;
102. Considering the process described in EN 16708, § 4 clause 5.7, is closer from disinfection than sterilization;
103. Considering a recognised and properly described process of disinfection must be introduced in EN 16708;

We require CEN to withdraw this standard until it introduces disinfection process where necessary.

VII. Defective hygiene procedures: procedures delivered at client's home or in outdoor locations

104. Considering the scope of the standard relates to the delivery of procedures "regardless of where the service is delivered"[23] [24],
105. Considering the delivery of procedures becomes possible at client's home, in camping, festivals, and any outdoor locations;
106. Considering hygiene is not controllable on the same way in beauty salon, client's home or outdoor locations;
107. Considering there is no normative requirement restricting the scope of procedures delivered at client's home or outdoor locations;
108. Considering EN 16708 allows invasive procedures and procedures with accidental contact with blood or bodily fluids;
109. Considering EN 16708 gives to beauticians the role of proceeding to risk assessment and restricting the scope of outside procedures;
110. Considering under EQF 3 qualification a professional has no possibility to proceed to risk assessment;
111. Considering to proceed to risk assessment requires EQF 6);
112. Considering there is no minimal training requirement in EN 16708 (see clauses 34 & 35)
113. Considering EN 16708 must include the risk assessment and risk management of procedures performed outside beauty salons;

We require CEN to withdraw this standard until it limits the scope of procedures being delivered outside of beauty salon and manages the risk of procedures performed outside beauty salons.

VIII. Defective hygiene procedure: risk assessment process

114. Considering there is no normative requirements for hygiene in procedure room: "In establishing each treatment area consideration shall be given to the layout set-up and hygiene requirements for the beauty treatments to be offered"[25];
115. Considering the template proposed Annex B (informative) does not describes a risk assessment for hygiene[26];
116. Considering there is no normative description of risk assessment for hygiene [27];

[23] § 1 clause 1 : scope
[24] As defined in clause 2.9
[25] § 1 clause 5.5
[26] Annex B
[27] Clause 4.3

117. Considering the standard gives responsibility to the service provider's to proceed to risk assessment;
118. Considering to proceed to risk assessment for physically invasive process requires normative obligation of qualification related to the procedure (EQF 6/7);
119. Considering there is no minimum qualification in the standard (see 34 & 35).

We require CEN to withdraw this standard until hygiene risk assessment process is introduced

IX. Defective hygiene procedure: water supply

120. Considering there is no normative requirements concerning water supply in procedure area "In establishing treatment areas, the following shall be considered in line with the demands of the beauty treatment": "supply of water for each treatment room (…) where required"[28];
121. Considering the standard has no normative requirements to prevent the use of water supply as kitchen or toilet washbasin for cleaning purposes;
122. Considering the standard must include water supply to wash hands in procedure area;
123. Considering water supply to wash hands must be different from kitchen or toilet washbasin.

We require CEN to withdraw this standard until independent water supply is introduced

X. Defective hygiene procedures: chemical and hazardous substances

124. Considering the standard gives to the service provider's responsibility to establish the procedure "to control the storage, labelling, dispensing, handling and disposal of all chemicals and hazardous substances of chemical and hazardous substances";
125. Considering the standard does not introduce definition of "chemical and hazardous substances"[29];
126. Considering to establish such a procedure requires EQF 6;
127. Considering there is no minimum qualification in the standard (see 35 & 36);
128. Considering the standard must include a safe procedure to manage chemical and hazardous substances.

We require CEN to withdraw this standard until it includes procedure to manage hazardous substances

XI. Defective hygiene procedures: hygiene review of service

129. Considering there is no normative obligation review of service "the following should be considered"[30];
130. Considering there is no normative obligation of periodicity for review of service "this should take place at least once per year"[31];
131. Considering there is no normative obligation of minimal documentation for review of service: "A plan outlining actions and targets for improvement, timelines and the responsible parties should be documented"[32];

[28] § 2 and 3 clause 5.5
[29] Clause 6.3
[30] § 2 clause 7.2
[31] § 1 clause 7.3
[32] § 1 clause 7.4

We require CEN to withdraw this standard until it includes normative obligation of review of service concerning hygiene and safety

XII. Defective hygiene procedures: misuse of medical wording

132. Considering over the past several years, the popularity of cosmetic non surgical skin treatments has experienced an unprecedented growth. As the acceptance and demand of such treatments grows, so does the size and diversity of the market providing these treatments, and this has led to a raise in adverse effects;
133. Considering In the Committee review of cosmetic procedure, Sir Bruce Keogh's recommends three key areas of improvement[33]: "*the second key area in which changes are needed is to have an informed and empowered public to ensure people get accurate advice and that the vulnerable are protected*";
134. Considering the standard uses systematically medical terms[34];
135. Considering service providers have no minimal qualification (see 30), nor medical or healthcare training, the standard creates confusion in public mind;
136. Considering the standard will justify unscrupulous and unsafe practices using such medical terms; including to protect such unscrupulous from prosecution.

We require CEN to withdraw this standard until it excludes misuse of medical wording

[33] See note 12

[34] "Treatments", "beauty therapists", "consultation", “chemical peels”, etc.