**Webinar of 2022-10-05**

**'CEN and CENELEC workshop on Personal Protective Equipment (PPE) – Medical Devices (MD) dual use products'**

**Questions & Answers**

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| 1 | How do you feel about distinguishing personal protective clothing (PPC) from PPE? | Personal protective clothing is part of PPE and thus the same legislative framework applies. At this time, it seems to make more sense to talk about PPE in general, but as said in the future we might have workshops on more specific topics. |
| 2 | PPE can be used as MD if it meets the legislative requirements for MD and PPE at the same time. And vice versa. Specifically, for example, the respirator must pass tests according to EN 149+A1 and EN 14683+AC or using EN ISO 22610 and the legal requirements set out in Regulation (EU) 2016/425 and Regulation (EU) 745/2017. And vice versa. A product certified as MD must pass PPE certification. Otherwise, dual use of the product cannot be allowed, it cannot be claimed that the surgical mask is a respirator. Do you agree with this statement? | Yes, agree. |
| 3 | Is there an opportunity to combine the legislation for Type I/II/IIR, FFP1/2 and N95 standards to ensure compliance across the world? | Regulation (EU) 2016/425 on personal protective equipment and Regulation (EU) 2017/745 remain different and separate pieces of legislation covering different types of products. What it could be possible to "combine", is the harmonised standards supporting those legislations for specific products, for instance face masks, with a set of clauses aiming at covering the respective applicable legal requirements. |
| 4 | If we have a dual glove, as a Cat. III epi and a Class I medical device. We have two manufacturers, one responsible for epi, as it is a client brand, and another manufacturer as a medical device because it has the | A single legal or natural person must assume the role of manufacturer according to the applicable EU legislation, the so-called "legal manufacturer", with the related obligations in placing the product on the market; while the other could be an "actual manufacturer", through a specific contractual agreement with the "legal |

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| | license. Can two manufacturers appear on the label? If not, how to do it?<br><br>Should be put two CE markings? | manufacturer" (see section 3.1. of "The 'Blue Guide' on the implementation of EU product rules 2022" https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2022.247.01.0001.01.ENG&toc=OJ%3AC%3A2022%3A247%3ATOC.<br><br>With respect to CE marking, in any case a single CE marking must be affixed on the product, as CE marking is intended to indicate compliance with all the applicable requirements of EU legislation providing for CE marking (see https://single-market-economy.ec.europa.eu/single-market/ce-marking_en). |
| 5 | Once there was an interpretative document by COM on products being both PPE and MD. This document gave interpretations how such products should be handled in terms of both applicable legislations. Are COM services think of formulating such a document for current PPE and MD Regulations again? | Yes, it is still available on https://ec.europa.eu/docsroom/documents/10262/attachments/1/translations. It is an old document, to be updated and revised, even if its contents are still valid overall. It is a pending task for the colleagues in PPE and MD sectors, we hope to be able to have a revised updated version very soon. |
| 6 | The last update of the publication on the OJ of the standard providing presumption of conformity of PPE was made more than one year ago. In the meantime, many standards were published and should replace standards very old. When is it expected a new update of the list? What should we do in the meantime? Some new standards are replacing standard of more than 20 years old (i.e. EN ISO 18527-1:2022 should replace the EN 174:2001 standard) | After the publication of a European standard, the European standardisation organisation needs to submit to the Commission the references of the standards for citation, the Commission verifies that the standard fulfils the conditions for publication in the OJEU, and if positively assessed, the Commission needs to prepare the decision to publish the references on the OJEU. The time lime for this process depends on many factors and varies with each standard. It is therefore difficult to say when the references of standards will be cited in the OJEU.<br><br>For information, an update of the list of references of harmonised standards for PPE, as "Commission Implementing Decision (EU) 2022/1914 of 6 October 2022 amending Implementing Decision (EU) 2020/668 as regards harmonised standards on personal flotation devices – buoyancy aids, lifejackets and |

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| | | accessories", was published on the *Official Journal of the European Union* OJ L 261, 7.10.2022, p. 60 https://eur-lex.europa.eu/eli/dec_impl/2022/1914/oj. |
| 7 | How can we to ensure that we get sustainability and reusability embedded in the standards across the board? We need to look to increase the amount of reusable products and the circular economy of products even in healthcare settings. | Within the overall CEN-CENELEC system there is the SABE TG circular economy active on sustainability. Specific for PPE, the Sector Forum PPE has set up a TG on sustainability, currently working on guidance for the TCs involved in PPE on how to deal with sustainability. |
| 8 | In the §5.2.3 Breathability of EN 14683:2019+AC:2019 it's stated that if the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure. In this situation what is a classification of the masks as per EN 14683? This classification depends also on the breathability value. | It is an interesting question. Could you please forward it to me at Mario.Gabrielli-Cossellu@ec.europa.eu to have a more detailed look? Many thanks. |
| 9 | Agree to have a standard for dual products | Many thanks, it is not an easy task, but we are considering such a possibility, and this workshop is an important step. |
| 10 | Is it mandatory to certify with iso 13485? | No, the use of standards in the EU is voluntary, according to Article 2(1) of Regulation (EU) no 1025/2012 on European standardisation https://eur-lex.europa.eu/eli/reg/2012/1025/2015-10-07.<br><br>Indeed, compliance with legislation (e.g. EU Regulation on PPE and/or MD) is mandatory. Standards are usually an effective way to prove compliance with the legislation, but are always voluntary. It is always an option for a manufacturer to prove compliance with the legislation using other technical specifications. |
| 11 | Old interpretative document: Information on the relation between the revised Directive 93/42/EEC concerning medical devices and Directive 89/686/EEC on personal protective equipment | Correct. It is an old document, to be updated and revised, even if its contents are still valid overall. It is a pending task for the colleagues in PPE and |

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| | https://ec.europa.eu/docsroom/documents/10262/attachments/1/translations | MD sectors, we hope to be able to have a revised updated version very soon. |
| 13 | With regard to the ophthalmic industry, do you consider the classification of glazable sunglasses as dual use product MD/PPE, as handled so far, to be unchanged valid and applicable? Do these products therefore still have to meet both specifications (PPE/MD) for essential safety and performance requirements? | Under the present legislative framework, yes, these products have to meet the applicable requirements of both PPER and MDR. But developments are possible to "simplify" the situation taken into account the specific characteristics of such products. |
| 14 | If our supplier has carried out the tests of the EN 455 1.2.3.4 and EN 374 regulations, would we have to repeat them, since we appear as manufacturers? | No, it is not necessary. The manufacturer has to assume the responsibility for the tests carried out by other actors. The manufacturer should carry out again such tests if it is not fully sure about them. |
| 15 | Comment: Mfr data, regulatory data, applied standards etc - should be stated in the DoC. | Correct, in the DoC and supported in the technical documentation. |
| 16 | If dual use, could there be 2 CE marks (e.g. CE 1234 and CE 6789) when PPE conformity assessment and MD conformity assessment are performed by 2 different Notified Bodies? | CE marking on a product must always be a single one. On the other hand, it could be possible to have the identification number of more than one notified body following the CE mark, where there is not a single notified body that has all the competences to perform the complete conformity assessment of a product, and the applicable union act/s require to include the identification number of the notified body on the product. This should be studied on a case by case basis. In the associated EU declaration of conformity, compliance with more than one EU legislation, with the related standards etc., must be stated. |
| 17 | Can you confirm: One CE. one manufacture on the label. If I have two suppliers, I need to assess the product as "one". So, tests from suppliers are not accepted, right? We need to perform the tests in final product and take the responsibility for DoC. Am I thinking, correct? | Yes, overall correct - in case of tests carried out by someone else, the manufacturer assumes the responsibility on them. |

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| 18 | The interpretative document of the Commission's Services it's really an old document (and due to my specific request in 2009) | Indeed, it is a bit archaeological... but in substance is still valid. It is a pending task for the colleagues in PPE and MD sectors, we hope to be able to have a revised updated version very soon. |
| 19 | We need to have an update in relation with the new regulation. It will very helpful. | Yes, updates on the EU Regulations are regularly provided in the Commission's sectorial websites, PPE: https://single-market-economy.ec.europa.eu/sectors/mechanical-engineering/personal-protective-equipment-ppe_en, contact: grow-PPE@ec.europa.eu. MD: https://health.ec.europa.eu/medical-devices-sector_en, contact: SANTE-MED-DEV@ec.europa.eu. |
| 20 | Remark related to some proposals in FAQ: If a device claims to be useful in hospital it shall fulfil MED, if it also claims to be a kind of PPE, then also the PPE regulation, if it is supported with energy (batteries) it shall also be EMC or LVD compliant, if it has furthermore a pressure cylinder it shall also fulfil PED. So it doesn't end with MD/PPE Regulation. We should not go for duplicate/multi–CE Markings. The use and the claim of the manufacturer should cover all claimed regulations (use instruction, DoC). | You are fully right, it does not end with the PPE/MD Regulations, but also other EU legislative acts may apply. CE marking is always a single one to indicate compliance of the product with the applicable EU legislation providing for CE marking. |
| 21 | Yes, agree with Marco, the EU will publish a new interpretative dual document for dual products? | Yes, we will update the current (old) one as soon as possible. |
| 22 | During the deep covid 19 phase in some hospital we faced problems on ffp3 masks with shrinked valve (instead of previous common glued ones) tests performed by my group demonstrated that the present code doesn't cover sufficiently the necessary test for this type of mask, if you desire I can explain directly by voice in this meeting. | Thanks for the question. Clearly the shortage of supply of PPE to healthcare professionals during the height of the pandemic resulted in some far from ideal products being used in hospital settings. As you may know, standards and directive do not tend to stipulate a specific design of product, rather that the product meets the minimum requirements of the harmonised standards. It sounds like the products that your group tested failed to do this. There were a number of complaints on the RAPEX system about substandard products, so this may not have been unusual. If the products that your group tested were CE approved PPE, if you have not done so already, it may be worth contacting |

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| | | both the manufacturer, and the notified body whose CE mark appears on the product to report your findings. The *Technical Committee TC 79* would like to hear any suggestions that you may have to improve the test methods in this area for use in any future standards, if you feel that the testing could be improved.. The use of exhalation valves at all, when considering permissible levels of outward leakage may be something to be considered in future standards for the healthcare environments. |
| 23 | For sure relevant stakeholders (e.g. manufacturers, operators, users, subcontractors, suppliers), will be more confident in terms of the dual use PPE MD products, when more details and/or updates took place with regard to the legislative documents, the HS, the lists of the specific categories of dual use products and the potential need of new standards, and/or of the interoperability of standards, and/or of joint technical committees. | Yes sure. Appropriate and updated guidance is the key, for the smooth implementation of the relevant legislation. We have already several documents in the Commission's webpages on PPE and MD but we need to develop something more specific on the relationships/borderlines between them, and in particular on dual-use products. We are working on it. |
| 24 | Considering that dual use PPE/MD products have a very different certification requirement, as frequently for PPE they are CAT III, while for MD CAT I. This means that there is more rigorous control of the PPE by a Notified Body than for MD, were this would be self-certified. This opens naturally the possibility for abuse, or even the feeling that the PPE that has a more rigorous control. Is the Commission going to harmonise the approach? | Sure, this is one of the questions that move this initiative: provide clarification, prevent confusion and abuses - as we sometimes noted especially in the worst Covid times. |
| 25 | How can we get involved in the sustainability taskforce? Very keen to add in our work in the UK | For the TG sustainability of the PPE sector forum, please contact the sector forum secretary : inga.troester@din.de |
| 26 | IS one NB for PPE responsible if a dual use product is not correctly certified for Medical Device use? Or is this the sole responsibility of the manufacturer? | The ultimate overall responsibility of compliance of a product - including the correct legal qualification and classification/categorisation of risks - is for the manufacturer. However, if a NB does not correctly perform its work, it may be also considered responsible, under the EU |

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| | | legislation (control of NBs by competent authorities, liability etc.) as well as national legislation on contractual agreements. |
| 27 | There may be a feeling that as PPE and MD both require quality assessment and control, in the case of PPE for CAT III this is annually checked by the notified body, while for MD in case of CAT I products is self-control/certification. This may create the feeling that if the PPE is certified as a CAT III, this is sufficient for MD. But this does not seem to be necessarily the case, do you agree and what is the difference? | Indeed, the difference in classification/categorisation of risk, with the intervention or not of a NB could be a problem and it can be source of confusion and misunderstanding out there. But a PPE certification as category III does not "cover" a MD conformity assessment as class I: they are two different legislations to be applied on the product, with the respective applicable conformity assessment procedures. As a result, we will have a single CE marking on the product, and a EU declaration of conformity, stating compliance with the PPER and with the MDR. |
| 28 | Is it possible to certify as DM a PAPR system (automatic respirators with helmet) for hospital? | It would depend on the characteristics and intended use of the product, in particular the protection it provides and to whom. |
| 29 | '@Mario Gabrielli-Cossellu, The work done so far from the EC, EU R&I and Standardisation ecosystems are exceptionally progressive given the pandemic and other challenges. | Many thanks! we try to do our best in these very difficult times. |
| 30 | Fantastic.... alexis.percival@nhs.net. I am working with the WG17 on facemasks but we are doing a lot of work across the UK on reusable PPE and products so there is lot to feed into it. | CEN TC205 WG17 (infection protection masks) will certainly be interested in your feedback |
| 31 | We are interested in participating in the WG 17, how can we apply? | You need to address your national standardization body to be nominated for participation on European level in the WG. |
| 32 | Would there be mandate for development of standards for reusable PPE (e.g. reusable respirators)? | Typically, standards give performance requirements, they are not stating that a product has to be reusable or not - so not sure that it is even necessary to foresee a separate mandate. But that's also the reason for working on |

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| | | sustainability in the PPE field, to ensure that tests mentioned in standards are indeed also applicable to reusable PPE. |
| 33 | I do have such device already (mask and respirator in one). Unfortunately have no funds to proceed with the research for it https://euipo.europa.eu/eSearch/#details/designs/007780150-0001 | Information on funding opportunities can be found here: https://health.ec.europa.eu/funding_en. |
| 34 | What about full facemasks for combined use so following EN-136 Full face mask protective devices but then only combining the medical breathing protection of DIN 14683? Would the new directive cover this and if so where could we read more about it? | In principle the current PPE and MD Regulations cover such cases. In the future we could have common harmonised standards, but it is still a work to reflect about, and in this sense this webinar is an important step. |
| 35 | I hear @Mario Gabrielli-Cossellu speak about the dual CE marking in response to Pilar's question. So, if I get this right, a product must only have 1 CE mark on the Label? But, the NB must come to an agreement on which one in case of dual products. | Only one CE marking must be affixed on the product, to indicate compliance with all the applicable EU legislation, one or more acts. The different applicable EU legislation must be indicated in the EU declaration of conformity. In case of these dual PPE/MD products, the NB intervenes for the conformity assessment of the PPE aspects of the products, and issue the related certificate. But it is always the manufacturer that affixes the CE marking, on the basis of the results of the conformity assessment procedures carried out, by the NB for PPE and by itself for MD. |
| 36 | '@Giovanna Longo - Grazie mille. What about the role of gender in the development of the standards you have discussed? Could you comment on this? I am thinking about the UNECE Gender-Responsive Standards Initiative. | Dear Louis, thanks for the question. It is indeed a difficult but important one. As I spoke about fitting, it is important to have products fitting any kind of face. The product, at least according to EN 149, as tested according to a panel and their anthropometric measures are reported. This is at least a beginning if not the answer.<br><br>Note that there is some work also done in ISO. Please have a look at ISO TS 16976-2, which takes into account anthropometric factors: https://www.iso.org/obp/ui#iso:std:iso:ts:16976:-2:ed-2:v1:en |

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| 37 | @Miss Giovanna Longo and Mr Sven Schöppe, Do you see synergies with other TCs as it is for example with CEN/TC 391 'Societal and Citizen Security and its Working groups (CEN/TC 391/WG 1 - Healthcare Facilities)? | There might indeed be synergies with other TCs. Therefore it is important to have open communication about projects (e.g. in workshops like this one) so that all concerned parties can contribute and collaborate. |
| 38 | Exactly because of the possibility for a product to be both MD and PPE, is the notified body responsible to decide whether they shall certify the product as PPE and/or MD? If the product gets to be certified as both MD and PPE, one label wouldn't be enough for a proper information for a user. Isn't it possible to use 2 labels in these cases? | The notified body indeed has to provide its technical expertise but the ultimate decision is for the manufacturer, as the overall responsible of compliance of the product, including the legal qualification (which EU legislation/s is/are applicable) and the classification/categorisation. The related results must be reflected in a single CE marking, a single EU declaration of conformity with the supporting technical documentation, and a single label. In practice, when implementing this in real situations, some degree of flexibility is possible, as indicated in the "Blue Guide" https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2022.247.01.0001.01.ENG&toc=OJ%3AC%3A2022%3A247%3ATOC, see in particular sections 4.3., 4.4, 4.5. |
| 39 | Mr. @Sven Shoppe, Regarding the GER, UE regulation must be one. If German has one, Portugal other, and each country decides to have their own rules, the framework will not result. We are seeing this in Packaging with the Triman logo (for example). All countries must have the same rules... | I couldn´t agree more. |
| 40 | Sven are your proposing that for dual use product they should be test to the same test methods, and levels? | If we were able to use test methods and minimum performance requirements applicable to each of the dual uses for a product, it would be a first step. |
| 41 | Thanks for your response, Henk, would the reprocessing requirements and test methods capable to produce products | That should be the aim indeed. |

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| | suitable for their use in healthcare environment? | |
| 42 | One should not forget that the protection that is provided for MD is inside out, while for PPE it is outside in, therefore the testing is going to be different as the risks are different, therefore the levels can be different as the risk may be different (open wound, versus skin, healthy person versus unhealthy patient). The standard should take this into account. | Correct, thanks for your consideration. |
| 43 | The requirement for the exhalation valve airtightness is already taken into account during the revision of EN 149. | |
| | Masks: in CEN TS 17553 community face coverings: no valves (to avoid direct exhalation carrying virus in droplets). | |
| 44 | Can the same standard be harmonised under both the PPE and MD regulations? If so the conception of the standard may need to be adapted? | As said in video - yes, with several Annexes Z, and the necessary adaptations in conception and development of the standard, and in its assessment by the HAS consultants and the relevant Commission services. |
| 45 | Just to also point out there is no standard person size or face. We work on the Sheffield head in the UK for head related PPE/MDs and it is a male head.... it doesn't work for ladies or men with small heads. The same works for other devices | You are fully right and thanks a lot for pointing out this very important aspect. Gender perspective and related design, manufacturing and ergonomic issues are very important - we know that CEN and CENELEC duly take them into account when developing standards, and the Commission is also making important efforts in this sense, from legislation to standardisation requests etc. - but work is still to be done for effective implementation. |
| 46 | I believe Mario indicated that for example ISO 13688 covered both the MD or PPE? But I don't believe that there are both Annex Z for both regulations, I believe only the ZA is available. | No, for the time being we have no harmonised standards with Annexes Z covering both PPER and MDR. It is a possibility for the future. Sorry for the misunderstanding. |

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| 47 | Comment: The topic of sustainability naturally leads one to discussions of reusability of PPE, which in turn leads to discussions of reprocessing. TC 205 may want to consider liaisons with CEN TC 204 (ISO TC 198) Sterilisation of healthcare products and CEN TC 216 Chemical disinfectants - as applicable sterilisation and disinfection standards would come from these committees. It should also be noted that disinfectants used for the disinfection of PPE would come under the Biocidal Products Regulation (BPR) and disinfectants / sterilising agents for the bio decontamination of Medical Devices would come under the MDR | thank you for the comment, certainly to be considered by CEN TC 205, if not already the case. |
| 48 | Registration link to the SBS PPE and Textile Care forum - Going from Dual use to multi use →<br><br>http://www.sme-safety.eu/news_dett.php?news_id=49 | |
| 49 | '@Anna. As presented by Sven Schöppe, EN 14126 would be superseded with ISO 22615. | |
| 50 | The UK PPE Decision Making Committee agreed a specification for thumb loop gowns (very similar to isolation gowns) and published this in July 2021: http://www.smtl.co.uk/images/documents/standards/ThumbLoopedApron-Spec-2021-07-02.pdf - there is definitely a demand for some sort of isolation/thumb loop gown. | |
| 51 | Is it worth looking at particulate matter and micro plastic as well as coating release into washing waters to decrease pollution and release of forever chemicals? This would be a fantastic standard as we move to more laundered products | Currently there is work ongoing on standardisation of test methods to measure micro plastics e.g. in water. |
| 52 | '@ Anna, I think the practical approach was excellent. Times like covid were unprecedented and I think solutions o | |

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| | integration should be the need of the hour because during such difficult times, the PPE shortage / demand vs supply should be considered | |
| 53 | do not confuse "gender" and "sex". Adaptation to morphology is a matter of sex.<br><br>Definitions from ISO IEC 2382-37: 37.07.30 sex classification as male, female or some other category based on an assessment of primary sexual characteristics or genotype or both<br>Note 1 to entry: Sex is generally assigned at birth by a third-party assessment.<br>Note 2 to entry: Primary sexual characteristics are any of the body structures directly concerned with reproduction. 37.07.31 gender classification as male, female or another category based on social, cultural or behavioural factors<br>Note 1 to entry: Gender is generally determined through self-declaration or self-presentation and may change over time.<br>Note 2 to entry: Depending on jurisdiction recognition, may or may not require assessment by a third party. | Many thanks for this information, indeed very important and useful. |
| 54 | for MD class 1 we have some countries that require registration (at Ministry of Health) or at least they use to ask. Do we have a common approach for EU countries? The example is for FFP mask, we had countries asking for registration and other not. | For MD in the EU, registration requirements are going to be harmonised through the Eudamed system (see Art. 29 MDR). For PPE honestly, I am not sure about the latest situation but this should be harmonised as well, to ensure free circulation etc.<br><br>In the EU PPE Regulation, there is no requirement for registration of products or manufacturers (or other economic operators). Registrations should indeed be harmonised on EU level to maintain the Single Market principles. |
| 55 | One point I would like to share with all of you: it is important to take in account in the tests standards of PPE and MD the performance of the products and their | Good point. The MDR contains some provisions on reusable devices and reprocessing etc. and indeed it is very important to ensure compliance and control by market surveillance authorities. |

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| | certification after reuse in the case of reusable products. After the pandemic, these kind of products are growing in the market and we need to control them properly | As for Medical Devices it is of course essential that, every time the MD is placed on the market "as new" and "fully refurbished" after reprocessing, it needs to meet the minimum performance requirements of the applicable (harmonised) standards. PPE Regulation applies also to new and second-hand products. |
| 57 | Since 1990 we exam ergonomic dimensions especially in Technical Universities and during this big journey, European workers and companies (SMEs and Industries) have been enormous benefited. | Thanks for the information, TCs should consider this type of information for sure, so please make sure it is available for standardisation work. |
| 58 | when an Medical Device is added to a PPE that has already been placed on the market. What are the product responsibilities? Could other legislation also be involved such as trademark law. | Sure, both EU and national legislation, on liability, contractual agreements, etc., between the different operators, their roles and responsibilities. |
| 59 | '@Alexis Percival In WG17 Infection protection Devices the issue of microplastics is being considered from the perspective of reducing inhalation of fibres released from the mask/device. The suggestion is to cite ISO 18562-2 Biocompatibility of gas pathways whose limits are taken from the US EPA PM limits. I think we are many years from having limits based on observed environmental or health effects, we have to make do with best guesses until then | |
| 60 | National, regional standards does not help for having harmonisation globally. But there are less and less participation in writing standards, certainly at a global stage. The difficulty in harmonising under PPER and MDR, does not help having people volunteering in leading or contributing to standardisation, When we look at CEN, CENELEC, ISO and IEC, the active persons are rapidly ageing without having new | It is true, unfortunately. There are different aspects in standardisation to consider, including participation of all interested parties, accessibility, related costs, etc. - and they have not to be taken for granted. Especially in the EU with its model heavily relying on the availability of harmonised standards. The Commission also contributes in funding but still more efforts |

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| | people wanting to participate. This is true for PPE and MD standards. | should be done to ensure smooth operation at the different levels. |
| 61 | Microplastics from textile sources: see CEN TC248 WG37. | |
| 62 | I have one question for combination products. Considering the main changes introduced by the Regulation (EU) 2017/745 MDR (compared to the MDD) as for example that the “systems” can include non-medical devices and in particular “other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system … is otherwise justified” (22.1c), where the ‘system’ means a combination of products, either packaged together or not, which are intended to be inter- connected or combined to achieve a specific medical purpose.<br><br>Is it possible to use the article 22 statement to justify the combination of both PPE and MD devices? This will allow to avoid to have in place the agreements between two manufacturers (often competitors) and will allow to use certifications for medical devices and certifications for PPEs. I have in mind class I MDs for patient handling in pre-hospital procedures and class III PPEs for rescue procedures. | At a first glance I would say, yes. However, the formulation of Article 22(1)(c) MDR is rather general and it could be interesting and useful to elaborate a bit more on it, for instance through some guidance document specifically devoted to "dual-use" PPE-MD products. Please send me a message to Mario.Gabrielli-Cossellu@ec.europa.eu to consider it later on also with the specialised colleagues on combination products. Thanks! |
| 63 | Interdisciplinary and transdisciplinary approach brings always a holistic point of view not only in setting up standards but also in any decision-making processes. The EU New Standardisation Strategy indicate to all of us that we can be benefit with collaborative building capacities culture. H2020 and Horizon Europe Projects have delivered and are delivering exceptional | |

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| | outputs that could be valorised from nay CEN CENELEC ETSI TCs! | |
| 64 | Example: medical devices with personal protective equipment against falls – connectors, ropes, anchor devices etc. | Could some practical examples of such products be shared ? |
| 65 | EN ISO 18526-4 includes 6 adults head forms plus 2 children head forms to fit almost all populations. | |
| 66 | Similar in ISO 16900-5. 5 head forms for testing Respiratory Protective Devices, covering 5 to 95 percentile of the global population. | |
| 67 | ISO 16900-5 includes 5 sizes of dummy heads to be used for testing of RPE. | |
| 68 | An earlier question asks if "is it mandatory to certify with iso 13485?" and the response was no - it's voluntary. | Correct, thanks - reference to the Standardisation Regulation (EU) No 1025/2012 and its definition of "standard". We can add that in some cases, we can have "mandatory" standards in EU legislation - for instance in medical devices, for symbols to be used. But these cases are "the exceptions that prove the rule". See also section 2.2. of the "MDCG 2021-5 Guidance on standardisation for medical devices" https://health.ec.europa.eu/system/files/2021-04/md_mdcg_2021_5_en_0.pdf. |
| 69 | This is the EC Desk Officer for PPER. It may be interesting to have examples from economic operators with real cases of dual use products showing the obstacles that they find when placing these products on the market due to the double legal framework applicable (double documentation and conformity assessment costs?, hurdles with recognition of accreditation, certifications?, etc). It is clear so far the lack of the awareness for the economic operators in relation to the application of both regulatory frameworks, | Fully agree Iván. In the PPE sector, a first step could be indeed a RfU, then intended to be integrated into a guidance document or the PPE Regulation Guidelines itself. For Medical Devices we should pass through the relevant subgroup of the MDCG, but the aim would be similar. And, later on, we could even think on a common intersectoral guidance... Lot of things to do! |

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| | which could be solved partially with a short guide for dual use products as discussed in the past. The other obstacles are not that clear in the practice. We can analyse them from the EC side from top to bottom and try to propose solutions but it is more useful and realistic when we have these real cases in our hands and try to find what is the most quick and pragmatic solution. E.g. in the form of a RfU for notified bodies for the conformity assessment of dual use products... | |
| 70 | On the topic of communication and cooperation, I would like to take this opportunity to highlight ASTM International's Global Forum for PPE that just met yesterday: https://astmppecollaboration.org/. Anyone is welcome to participate! | |
| 71 | Another aspect: There are dual-use products that (on the side of medical product) don't have the aim of protecting the patient, but of supporting him. E.g. what Giovanna showed: hearing aids and corrective eye protection. Might there be differences to medical products like face masks, gowns etc.? | See the definition of MD in Regulation (EU) 2017/745. MD are not limited to products protecting the patient. |