



Medical Device Coordination Group (MDCG) – Subgroup on Standards DRAFT AGENDA

Date & time: **19 June 2020, 09:00 - 13:00**

Venue: Remotely via WebEx

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|--|----------------------------|
| 1. Welcome | COM SANTE B.6,
All |
| • Introduction of the participants | |
| • Adoption of the Agenda | |
| 2. MDCG governance and subgroups | COM SANTE B.6 |
| • Overview and main activities | |
| • Administrative matters, website, Register, CIRCABC | |
| 3. General framework for harmonised European standards | COM SANTE B.6,
GROW B.3 |
| • Reference documents | |
| • Cooperation COM - CEN/CENELEC and the ABHS | |
| • HAS consultants | |
| • Publication of references in the OJEU | |
| 4. Harmonised standards under the current Directives | COM SANTE B.6
All |
| • Latest publication of references in the OJEU | |
| • Ongoing work for the next publication | |
| • Discussion | |
| 5. Harmonised standards under the new Regulations | COM SANTE B.6
All |
| • Standardisation Request in support of MDR and IVDR:
adoption, notification and acceptance processes | |
| • Standardisation items and requirements | |
| • Discussion | |
| 6. International activities | COM SANTE B.6,
All |
| • Cooperation CEN/CENELEC - ISO/IEC | |
| • IMDRF | |
| 7. AOB | All |
| 8. Date of next meeting and close | COM SANTE B.6 |