SNI for Medical Devices

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Standardisation and Conformity Assessment System
In Indonesia

SNI Planning → SNI Formulation → SNI Determination → SNI Maintenance

National Policy
- RnD
- Collaboration

Coaching

LPK Accreditation → LPK doing Conformity Assesment → Traceability of conformity assessment

Application of SNI Voluntary → Effectiveness, Application, Supervision

Application of SNI Mandatory

RESULT OF CONFORMITY

National Standard Unit Of Measure

Standard for Sustainable Development and Better Life
Why a Standardization Approach and Conformity Assessment is Needed?

There is synergy and collaboration between stakeholders.

Standardization and Conformity Assessment in the areas of:
- Trading
- Industry
- Consumer protection
- Legal metrology
- Science and technology
- Environment
- Communication
- Defense
- Health
- Agriculture
- Social Community
- Production efficiency improvement Defense and security
- etc

The main scope of the Law on standardization and conformity assessment (Law 20/2014)

Indonesian National Standard (SNI)
- Testing
- Inspection
- Certification
- Product
- Service
- Process
- System
- Personal

LPK Accreditation

Stakeholders

Legislation and sectoral regulations

SPK for sectoral regulation implementation

Standard for Sustainable Development and Better Life
Basic Principles of Formulation of SNI

1. Transparency
2. Openness
3. Consensus and impartiality
4. Effectiveness and relevance
5. Coherence
6. Development Dimension

- Clear rules and procedures, accessible to all parties
- Each stage of the formulation can be followed by all stakeholders according to the rules and procedures
- Taking into account the views of all parties, decision making is based on consensus

Note:
- Principles 1 to 6 refer to the decisions of the TBT Committee on the principles of developing international standards
- Referring to ISO Publication on Good Standardization Practices:
  - Stakeholder engagement
  - Legal process
  - Implementation at the national level

Involving all stakeholders, including considering the ability of SMEs in its implementation

Referring to relevant international standards and avoiding duplication between Komteks in the formulation of SNI

Considering the development of science and technology, able to meet market needs and regulatory requirements
NOTES:
PBSN 04/2018 concerning the Management of the SNI Formulation Committee:
- The number of Komtek membership is a minimum of 9 people and a maximum of 15 people (odd)
- The number of one stakeholder element should not exceed 50%
Adoption of international standards identically to the republication-reprint method;

Adoption of international standards identically to translation methods;

Adoption of modified international standards with translation methods;

Formulation of SNI with own development method.
SNI in Health Sector (2021)

- TC 13-12: Personal Protective Equipment and Work Protective Equipment
- TC 13-09: Biosafety and Biosecurity
- TC 13-01: Occupational Health and Safety
- TC 11-14: Aids for Persons with Disabilities
- TC 11-13: Sterilization of Healthcare Products
- TC 11-12: Dentistry
- TC 11-11: Household Hygiene Products
- TC 11-10: Medical Equipment Management System
- TC 11-09: Non-Electromedical Medical Devices
- TC 11-07: Optical and Photonic Products for Health
- TC 11-06: Contraception
- TC 11-04: In Vitro Diagnostic Test System
- TC 11-03: Electromedical medical device

TOTAL: 385 SNI
<table>
<thead>
<tr>
<th>Komite teknis</th>
<th>Mirroring TC/SC ISO atau IEC</th>
<th>Jumlah SNI adopsi</th>
</tr>
</thead>
<tbody>
<tr>
<td>11-04 Invitro Diagnostic Test System</td>
<td>ISO/TC 194 Biological and clinical evaluation of medical devices ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test system</td>
<td>25</td>
</tr>
<tr>
<td>11-06 Kontrasepsi</td>
<td>ISO/TC 157 Non-systemic contraceptives and STI barrier prophylactics</td>
<td>3</td>
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<tr>
<td>11-07 Produk optik dan Fotonik untuk Kesehatan</td>
<td>ISO/TC 172/SC 7 Ophthalmic optics and instruments</td>
<td>11</td>
</tr>
<tr>
<td>11-09 Alat Kesehatan non Elektromedik</td>
<td>ISO/TC 76 Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use, ISO/TC 84 Devices for administration of medicinal products and catheters, ISO/TC 150 Implants for surgery, ISO/TC 170 Surgical instruments</td>
<td>21</td>
</tr>
<tr>
<td>11-10 Sistem Manajemen Peralatan Kesehatan</td>
<td>ISO/TC 210 Quality management and corresponding general aspects for medical devices</td>
<td>6</td>
</tr>
<tr>
<td>11-11 Produk Higiene Perbekalan Kesehatan Rumah Tangga</td>
<td>Ruang lingkup meliputi produk perawatan bayi dan ibu, antiseptik, desinfektan, pestisida rumah tangga, kapas, tisu dan produk tisu lainnya</td>
<td>0</td>
</tr>
<tr>
<td>11-12 Kedokteran Gigi</td>
<td>ISO/TC 106 Dentistry.</td>
<td>36</td>
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<tr>
<td>11-13 Sterilisasi Produk Pelayanan Kesehatan</td>
<td>ISO/TC 198 Sterilization of health care products</td>
<td>8</td>
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<tr>
<td>13-01 Keselamatan dan Kesehatan Kerja</td>
<td>ISO/TC 283 Occupational health and safety management</td>
<td>0</td>
</tr>
<tr>
<td>13-09 Biosafety and Biosecurity</td>
<td>Ruang lingkup meliputi sistem keamanan dan keselamatan di laboratorium atau instansi terkait bahan biologi berbahaya</td>
<td>38</td>
</tr>
</tbody>
</table>
SNI for Health by Types (2021)
SNI for the Handling of COVID-19 Pandemics

- Medical mask; 1
- Respiratory protection (Respirator); 2
- Eye protector; 3
- Medical gloves; 5
- Protective clothing; 17
- Protective gloves; 5
- Ventilator, 13
- General guidelines and lab management; 3
- BSC dan biotechnology, 7
- cloth mask; 1
- Hand sanitizer, 14
- Medical gas apparatus and equipment; 9

TOTAL: 80 SNI
TERIMA KASIH
THANK YOU

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