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Kajian infrastruktur pemberlakuan Standar Nasional Indonesia (SNI) alat kesehatan

Ginting, Beluh Mabasa, author

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Abstrak

Pendahuluan. Kajian Infrastruktur Pemberlakuan SNI Alat Kesehatan ini mengacu kepada Pedoman Standardisasi Nasional (PSN) 301 tentang Pedoman Pemberlakuan Standar Nasional Indonesia (SNI) Wajib bertujuan untuk mendapatkan persepsi kesiapan stakeholder dalam hal ini Badan Standardisasi Nasional, Laboratorium Penguji, Lembaga Sertifikasi Produk, Regulator/Kementerian Kesehatan, Pabrik Alat Kesehatan, Rumah Sakit Pemerintah dan Swasta sebelum draft pedoman teknis pemberlakuan SNI alat kesehatan dirumuskan oleh Kementerian Kesehatan RI. Dihasilkan suatu usulan berupa pedoman teknis pemberlakuan SNI alat kesehatan.
Metode. Menggunakan kerangka konsep yang dijabarkan dalam rancangan penelitian berupa post test onlym tanpa control dengan jenis penelitian secara kualitatif dengan definisi operasional yang berisi pertanyaan penelitian yang ditujukan kepada stakeholder sebagai subjek penelitaan untuk pengumpulan data melalui studi dokumentasi dan wawancara mendalam menggunakan formulir sebagai instrumen penelitian kemudiaan data diolah, dikelompokkan, dianalisis dengan interprestasi, triangulasi dan flow chart kemudian dibahas dengan bembandingkan hasil penelitian dengan kepustakaan.
Hasil. Penelitian menunjukkan bahwa pedoman teknis tentang Pemberlakuan SNI alat Kesehatan segera dirumuskan oleh Kementerian Kesehatan dimulai dari peralatan yang berteknologi sederhana sampai sedang dalam rangka menjamin keamanan, mutu dan manfaat (safety, quality, efficacy) alat kesehatan impor dan ekspor yang beredar di Indonesia. Usulan Pedoman Teknis tentang Pemberlakuan SNI Alat Kesehatan dengan memperhatikan ketersedian Lembaga Penilaian Kesesuaian seperti Laboratorium Uji Produk Lingkup Alat Kesehatan yang terakreditasi dan Lembaga Sertifikasi Produk (LSPro) Alat Kesehatan yang terakreditasi.
.....The Infrastructure Study of Medical Device Indonesia National Standardization (SNI) Application referred to National Standardization Guidance (PSN) No.301 on Indonesia National Standardization application mandatory in order to get perception of stakeholder preparation such as National Standardization Agency of Indonesia, Testing Laboratory of medical device product, Product Certification Institution, Regulator/Ministry of Health, Domestic Manufacture of Medical Device, Government Hospital, Private Hospital before Technical Guidance draft of Medical Device SNI application is formulated by Ministry of Health. Draft proposal of technical guidance of medical device SNI application is produced.
Method. Using concept frame which is described in research design such as post test only without control with research kind qualitatively by operational definition contain research questions which directed to stakeholder as research subject for collecting data through documentation study and interview using form as study instrument and than the data is grouped, analyzed by interpretations, triangulation and flow chart after that discussed by comparative the result of research by library.
Result. The research showing that technical guidance of medical device SNI application must be formulated directly by Ministry of Health be began from simple to middle technology in order to make sure the safety,

quality and efficacy import and export medical device that distributed in Indonesia. The proposal of technical guidance of medical device SNI application by paying attention about the supply of the available compatibility assessment institution such as accredited medical device scope product test laboratory and accredited medical device scope product certification institution.