ULOGA NOTIFIKOVANIH TELA U SKLADU SA NOVOM REGULATIVOM IZ OBLASTI MS, IZAZOVI I UTICAJ NA TRŽIŠTE

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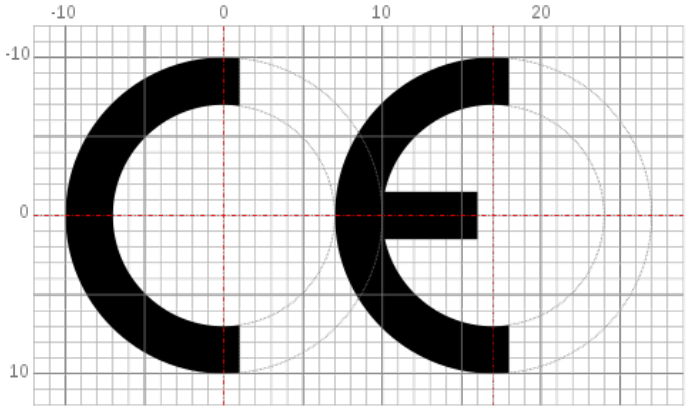
15. tradicionalni simpozijum ALIMS „Jubilej saradnje u interesu pacijenata“

Hotel Šumarice, Kragujevac, 11-12. 10. 2019

CE ZNAK?



- + Deklaracija o usaglašenosti (Declaration of Conformity), prema DECISION No 768/2008/EC

- Aktivna implantabilna medicinska sredstva
- Bezbednost igračaka
- Bojleri za toplu vodu
- Ekološki dizajn proizvoda u vezi sa energijom
- Eksplozivi za civilnu upotrebu
- Elektromagnetska kompatibilnost
- Emisija buke u okruženje
- In vitro dijagnostička medicinska sredstva
- Instalacije na kablovima namenjene prevozu ljudi
- Jednostavni sudovi pod pritiskom
- Konstrukcioni proizvodi
- Liftovi
- Lična zaštitna oprema
- Mašinski uređaji
- Medicinska sredstva
- Merni instrumenti
- Neautomatski instrumenti za merenje mase
- Oprema i zaštitni sistemi namenjeni za upotrebu u potencijalno eksplozivnoj atmosferi
- Oprema koja radi pod pritiskom
- Oprema za rekreaciju
- Pirotehnika
- Pribor za sagorevanje gasovitih goriva
- Radio oprema
- Restrikcija električnih supstanci za električnu i elektronsku opremu
- Uređaji za nizak napon

12. SIMPOZIJUM ALIMS - 28-29. 10. 2016

Nedoumice u vezi sa primenom EN ISO 13485:2016

5) Kako će nove medicinske regulative uticati na standard ISO 13485?

Koje će zahteve doneti nova regulativa? Kako će ovi zahtevi biti inkorporirani u EN ISO 13485:2016? Potrebna je promena standarda (nova verzija?), ta struktura će se uklopiti u novu regulativu (promena Annexa Z).

NOVA REGULATIVA

- Direktiva 90/385/EEC AIMDD (aktivna implantabilna medicinska sredstva);
- Direktiva 93/42/EEC MDD (opšta medicinska sredstva);
- Direktiva 98/79/EC IVD (invitro dijagnostička medicinska sredstva).

→

- Regulativa (EU) 2017/745 – opšta i aktivna implantabilna medicinska sredstva
- Regulativa (EU) 2017/746 – *in vitro* dijagnostička medicinska sredstva

NOVA REGULATIVA

- Regulativa (EU) 2017/745 – opšta i aktivna implantabilna medicinska sredstva – puna primena od 26. maja 2020.

- Regulativa (EU) 2017/746 – *in vitro* dijagnostička medicinska sredstva– puna primena od 26. maja 2022.

UTICAJ NOVE REGULATIVE

- Evropska komisija
  - Uspostavljanje novih tela (ekspertske grupe)
  - Definisanje novih propisa (standardi, smernice…)
- Notifikovana tela
  - Nova dezignacija
  - Praćenje proizvođača u novom okruženju
- Proizvođači
  - Tranzicija na nove propise
  - „sredstva bez nameravane medicinske upotrebe“

MDR – KLJUČNE NOVINE

- Stroža pravila klasifikacije
- Uvođenje panela nezavisnih eksperata
- Formiranje baze podataka i obavezna registracija: sredstava, proizvođača, ovlašćenih predstavnika, uvoznika i distributera (EUDAMED)
- Uvođenje Opštih specifikacija (Common specifications) pored harmonizovanih standarda
- Osoba odgovorna za usaglašenost sa propisima
- Jedinstvena oznaka MS (UDI)
- Klinička evaluacija i post-marketinško kliničko praćenje

EVROPSKA KOMISIJA

- Dezignacija notifikovanih tela
- Donošenje opštih specifikacija (Common specifications)
- Usvajanje harmonizovanih standarda
- Uspostavljanje ekspertskih grupa
- Uspostavljanje EUDAMED baze
- MDR and IVDR implementing measures rolling plan – Last update: 12/08/2019

EVROPSKA KOMISIJA

Activity	Deadline	Status
Notified bodies scope of designation	26 November 2017 (Legal deadline)	Adopted and published on 24 November 2017 COMPLETED
Reprocessing of single-use medical devices	November 2019 It shall be noted that, in the event that those CS are not adopted by 26 May 2020, reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions	Implementing act undergoing formal adoption procedure.
Common specifications for products without a medical purpose	Q1 2020	Discussion with Member States took place in May and June 2019. Implementing act undergoing formal adoption procedure.
Setting up of expert panels	Q3 2019	Implementing act undergoing formal adoption procedure.
Setting up of expert laboratories	TBD (not before 2020)	Survey with MDCG members and stakeholders finalised. While the issue of expert laboratories is under investigation, the appointment of expert laboratories does not constitute a priority
Setting up of new structures under IVDR: - EU reference laboratories	Q4 2019/Q1 2020	Call for nominations in preparation

EVROPSKA KOMISIJA

Activity	Deadline	Status
Rules to facilitate fulfilment of tasks by EU reference laboratories and to ensure their compliance with criteria	Q4 2019/Q1 2020	Implementing act in preparation
Fees for expert panel services	Q4 2019	Survey with MDCG members and stakeholders finalised. This is intended to support the drafting of the future act.
Fees for EURL services	Q2 2020	Implementing act in preparation
Unique Device Identification (UDI) System: designation of issuing entities	May 2019	Implementing Act adopted on 6 June 2019 COMPLETED
EUDAMED	Q4 2019	Implementing act in preparation
Common specifications for IVD Class D	Q4 2019	As soon as the last Common Technical Specifications are adopted under the current Directive 98/79/EC (adoption expected beginning Q3 2019), the new Common Specifications under the Regulation will be drafted. Common Technical Specifications under the current Directive 98/79/EC on combined tests were adopted in July 2019.

EVROPSKA KOMISIJA

Activity	Deadline	Status
Notified Bodies designation	As many Notified Bodies as possible designated prior to May 2020	52 applications received by the Commission services, 33 joint assessments carrried out. Four Notified Bodies already designated. Full scope of MDR and IVDR covered in the applications.
EUDAMED: Implementation plan	Legal deadline for first release: 26 May 2018.	First release done in due time (25 May 2018). Work in progress for further releases to reflect adaptations.
EUDAMED: drawing up of functional specifications	Q1 2019 (high-level functional specifications)	Version 4.1 (a new version 5 is to come) of high-level functional specifications were publically issued on DG GROW website beginning of March. It is indicated that modules for clinical investigation and market surveillance will not be available at the time of application of the MDR due to workability issues.
EUDAMED: Audit of functional specifications	Audit to start in Q3/Q4 2019. Must be finalised by Q1 2020.	Type of contract was determined. Request for service contract was launched

EVROPSKA KOMISIJA

Activity	Deadline	Status
EUDAMED go-live	Notice to be published by 25 March 2020	Work in progress to elaborate functional specifications and implement them First release go-live just after notice is published
EUDAMED: Setting of helpdesk	Before Eudamed go-live (March 2020)	Internal preparatory work has started.
Communication campaign	Updated information to be provided during the transitional period of the Regulations. Examples of deliverables are information factsheets, targeted presentations, dedicated website.	The new dedicated website and first updated library are live. A factsheet addressed to healthcare professionals and health institutions has been published in June. Social media campaign and targeted press release currently ongoing
Expert advisory structure: Setting of MDCG	26 November 2017 (Legal deadline)	Established by the legal deadline COMPLETED

EVROPSKA KOMISIJA

Activity	Deadline	Status
Expert advisory structure: Setting of MDCG subgroups	To be completed by Q1 2019	Subgroups operational as from 1st March 2019 COMPLETED
Mandate to SCHEER on phthalates	26 May 2018 (Legal deadline)	COMPLETED in September 2017. SCHEER's opinion expected in Q3 2019.
EU medical device nomenclature	Decision is expected by Q1 2019	Decision published on the DG GROW website in March 2019 COMPLETED
Standardisation mandate	Decision is expected by Q3 2019	Draft mandate undergoing adoption procedure.

NOTIFIKOVANA TELA

- https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34
- Notifikovana tela prema MDR, zaključno sa 30. 9. 2019:
  - BSI Assurance UK Ltd United Kingdom
  - DEKRA Certification GmbH Germany
  - IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A. Italy
  - TÜV Rheinland LGA Products GmbH
  - TÜV SÜD Product Service GmbH Zertifizierstellen Germany

PROIZVOĐAČI

- Medicinska sredstva klase I (nesterilna, bez merne funkcije) koja ne menjaju klasu
- Medicinska sredstva klase I (nesterilna, bez merne funkcije) koja menjaju klasu
- Medicinska sredstva viših klasa (uključeno notifikovano telo)
- Custom-made medicinska sredstva koja to više nisu (pojašnjenje definicije)

PRELAZNE ODREDBE (MDR čl. 120)

- Dezignacija notifikovanih tela prema MDD se poništava 26. maja 2020.
- EC sertifikati prema MDD važe do isteka, a najkasnije do 27. maja 2024, pod uslovom da se nastavi provera i primene PMS, vigilanca i registracija ekonomskih operatera prema MDR
- MS koja su stavljena na tržište tokom važenja EC sertifikata po MDD, mogu da ostanu na tržištu do 27. maja 2025.
- Klinička istraživanja započeta prema MDD pre 26. maja 2020. mogu da se nastave, izveštavanje mora prema MDR
- UDI mogu da dodeljuju GS1, HIBCC i ICCBBA do određivanja drugih tela

Klasa I → klasa I

- Medicinsko sredstvo mora da ispunjava zahteve MDR
- Sistem menadžmenta kvalitetom prema MDR
- Priprema TF prema MDR, uključujući deklaraciju o usaglašenosti
- UDI
- Registracija MS u EUDAMED
- Određivanje odgovorne osobe za usaglašenost sa regulativom
- Registracija proizvođača (+EU predstavnika, uvoznika i distributera) u EUDAMED

= stavljanje CE znaka i stavljanje na tržište posle 26. maja 2020. (ili pre)

Klasa I → više klase

- Medicinsko sredstvo mora da ispunjava zahteve MDR
- Sistem menadžmenta kvalitetom prema MDR
- Priprema TF prema MDR, uključujući deklaraciju o usaglašenosti
- Određivanje odgovorne osobe za usaglašenost sa regulativom
- UDI
- Ocena usaglašenosti od strane notifikovanog tela
- Registracija MS u EUDAMED
- Registracija proizvođača (+EU predstavnika, uvoznika i distributera) u EUDAMED

= stavljanje CE znaka i stavljanje na tržište posle 26. maja 2020. (ili pre)

Više klase

- Mogu da budu stavljane na tržište do isteka CE sertifikata, a najkasnije do 25. maja 2024.
- Mogu da budu u prometu najkasnije do 25. maja 2025.
- Nakon 26. maja 2020:
  - UDI
  - Registracija proizvoda i proizvođača u EUDAMED (rok 18 meseci)
  - Ugovori sa EU predstavnikom, uvoznikom i distributerima prema MDR (registracija ekonomskih operatera)
  - Odgovorna osoba za usaglašenost sa regulativom prema MDR
  - PMS i vigilanca prema MDR
  - Bez „značajnih“ izmena u MS
  - Redovna provera od strane NB koje je izdalo EC sertifikat

CUSTOM-MADE MEDICINSKA SREDSTVA

- MDD (= Zakon o MS Republike Srbije)
  - ‘custom-made device’ means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so. Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user ►M5 shall not be ◄ considered to be custom-made devices;
- MDR
  - ‘custom-made device’ means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs. However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;

SREDSTVA BEZ NAMERAVANE MEDINSKE UPOTREBE

- Kontaktna sočiva i druga sredstva namenjena za upotrebu u/na oku
- Proizvodi koji se delimično ili u celini uvode u telo hirurškim putem radi modifikovanja anatomije ili fiksiranja delova tela, osim proizvoda za tetovaže i pirsing
- Supstance i njihove kombinacije namenjene za supkutano, submukozno ili intradermalno injektovanje radi popunjavanja kože ili sluzokože lica i drugih delova tela
- Oprema za smanjenje ili uklanjanje adipoznog tkiva liposukcijom, lipolizom ili lipoplastikom
- Oprema za obnavljanje kože, uklanjanje tetovaža ili dlaka upotrebom EM zračenja visokog intenziteta
- Oprema za stimulaciju mozga magnetnim ili elektromagnetnim poljem koje prolazi kroz lobanju i modifikuje moždanu aktivnost

EKONOMSKI OPERATERI

- Proizvođači: čl. 10
- Ovlašćeni predstavnici u EU: čl. 11 i 12
- Uvoznici: čl. 13
- Distributeri: čl. 14

ODGOVORNO LICE ZA USAGLAŠENOST SA REGULATIVOM (čl. 15)

- Diploma (pravo, medicina, farmacija, inženjerske nauke i druge relevantne naučne oblasti) priznate od strane država članica EU, ili
- 4 godine profesionalnog iskustva u regulatornim poslovima ili QMS za medicinska sredstva
- Moguće angažovanje spoljnih saradnika za mikro i mala preduzeća

- MDCG 2019-7 Guidance on Article 15 MDR-IVDR Person responsible for Regulatory Compliance

No-deal BREXIT

- Nov znak usaglašenosti – UKCA
- Britanska notifikovana tela neće više biti priznata u EU
  - Svi prethodno izdati sertifikati biće nevažeći u EU
    (izvor: https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal)
- Britanija će nastaviti da priznaje CE znak tokom tranzicionog perioda
- Proizvođači van EU i UK će morati da imaju 2 predstavnika (u zavisnosti od tržišta na kome posluju), tj. predstavnici u UK više neće biti priznati u EU
- UK će doneti sopstvene propise koji su pandan MDR i IVDR
- Postojeća registracija u UK će morati da se obnovi, rok zavisi od klase (4 – 12 meseci)

SLOVENAČKI INSTITUT ZA KVALITET I METROLOGIJU (SIQ) – OBIM DELATNOSTI

Ocenjivanje i sertifikovanje sistema menadžmenta

Merenje

Bezbednost i elektromagnetika

Obrazovanje

Tehnologije igra na sreću

Hvala na pažnji!

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