

ANNEX A3: Legislation and Abbreviations

Legislation, regulations and standards

Suppliers of goods and services to Essity must comply with all applicable laws and regulations. The following list includes some, but not all, of the directives, legislation, regulations and standards applicable in the main markets where Essity does business. This list is not exhaustive and shall not relieve supplier of its obligation to comply with all legal and regulatory requirements applicable to the goods or services it provides.

It is supplier's obligation to check and ensure that the most recent, up-to-date versions of the laws and regulations referenced here are identified and complied with.

International management and harmonized standards

- ISO 9001 Quality management systems – Requirements
- ISO 13485 Quality management systems for medical devices – Requirements
- ISO 45001 Occupational Health and Safety
- ISO 50001 Energy management Systems
- ISO 14001 Environmental management systems – Requirements
- ISO 14971 Risk management for medical devices
- ISO 10993 Biological evaluation of medical devices
- ISO 22716:Cosmetics — Good Manufacturing Practices (GMP)

<http://www.iso.org/standards.html>

Product related directives and regulations

EU:

- 93/42/EEC: Directive concerning medical devices
- 2017/745/EC: Medical Device Regulation (into force in 2021)
- 2006/42/EC Machine Directive
- 94/62/EC: Packaging and waste directive
- 1223/2009/EC: Regulation on cosmetics
- 1907/2006/EC: Regulation concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) <http://echa.europa.eu/>
- 1935/2004/EC: Regulation on materials and articles intended to come into contact with food
- 2001/95/EC: Directive on general product safety

- 2011/65/EU : Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHSIII)
- 2012/19/EU: Directive on waste electrical and electronic equipment (WEEE)
- 2006/66/EC: Directive on batteries and accumulators and waste batteries and accumulators
- 2008/1/EC: Directive on integrated pollution prevention and control
- 2009/48/EC: Directive on the safety of toys 648/2004/EC: Regulation on detergents
- 2006/95/EC: Low voltage directive
- 528/2012/EC: Regulation concerning making available on the market and use of biocidal products
- 1272/2008/EC: CLP Regulation
- 2009/28/EC: Promotion of the use of energy from renewable sources
- 2019/1021/EU Regulation on persistent organic pollutants (POPs)

<http://eur-lex.europa.eu>

USA:

- Consumer Product Safety Act 2008
- FDA 21 CFR 820: Medical Device regulations
- FDA 21 CFR 176 – Paper and paperboard components
- FDA 21 CFR 700- Cosmetics
- FDA 21 CFR 310- New Drugs
- The Medical Device Reporting (MDR) regulation ([21 CFR 803](#))
- Toxic Substances Control Act
- Federal Insecticide, Fungicide and Rodenticide Act.
- Federal Hazardous Substances Act (FHSA)
- California Proposition 65 – Safe Drinking Water and Toxic Enforcement Act

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135680.htm>

Australia/New Zealand:

- TGO AS/NZS 2869-2008 Therapeutic Goods Order - Standard for Tampons
- AS/NZS ISO 8124 Standard on Safety of Toys
- NICNAS: National Industrial Chemicals Notification and Assessment Scheme
- Industrial Chemicals (Notification and Assessment) Act 1989 (the Act).

- Australian Consumer Law (ACL)
- Australian regulatory guidelines for medical devices (ARGMD)

China:

- SEPA order no 7 of the Measures on Environmental Administration of New Chemical Substances, “China REACH”
- CFDA: Order 650: Regulation on Medical Devices
- CFDA: Regulations Concerning the Hygiene Supervision over Cosmetics (1989)

System-related guidelines

EU:

- BfR Recommendations on Food Contact Materials
- BfR Guidelines for the evaluation of Personal Sanitary Products
- BfR Guidelines for the evaluation of Sanitary Papers
- IFS Household and Personal Care Standard
- BRC - British Consortium Standards

WW:

- GMP - Good Manufacturing Practice
- GLP - Good Laboratory Practice

Abbreviations

AOX - Adsorbable Organic Halides

AS - Australian Standard

BAT - Best Available Technology

BfR - Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment, Germany)

BOD - Biological Oxygen Demand

CAS - Chemical Abstracts Service

CFDA - China Food and Drug Administration

COD - Chemical Oxygen Demand

Cpk/Ppk - Process capability calculations

CSA - Canadian Standards Association

EC - European Commission

EMS - Environmental Management System

FDA - Food and Drug Administration US

FSC - Forest Stewardship Council

GHG - Green House Gases

GMO - Genetically Modified Organisms

GMP - Good Manufacturing Practice

IFS - International Featured Standards

ISO - International Organisation for Standardisation

IPPC/BAT - Integrated Pollution Prevention and Control/Best Available Technology

NICNAS - National Industrial Chemicals Notification and Assessment Scheme

NZS - New Zealand Standard

PEFC - Programme for the Endorsement of Forest Certification Schemes

REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals

RSPO - Roundtable of Sustainable Palm Oil

SDS - Safety Data Sheet

SEPA - State Environmental Protection Administration (China)

SFI - Sustainable Forestry Initiative

SPC - Statistical Process Control

TGO - Therapeutic Goods Order

TOC - Total Organic Carbon

TSCA - Toxic Substances Control Act (USA)