Role of Harmonized Standards in Promoting Manufacture and Trade of Medical Devices and Equipment in Africa

Medical Device Regulatory Convergence Project (MDRC) Good Regulatory Practices & Technical Competencies Pharmacy and Poisons Board & Regulated Sector

24th August 2023

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About ARSO

The African Organization for Standardization (ARSO) was established in 1977 by UNECA and OAU with the mandate to:

a. harmonize national and/or sub-regional standards as African Standards and issue necessary recommendations to member bodies for this purpose;

b. promote and coordinate standardisation and conformity assessment practices in Africa;

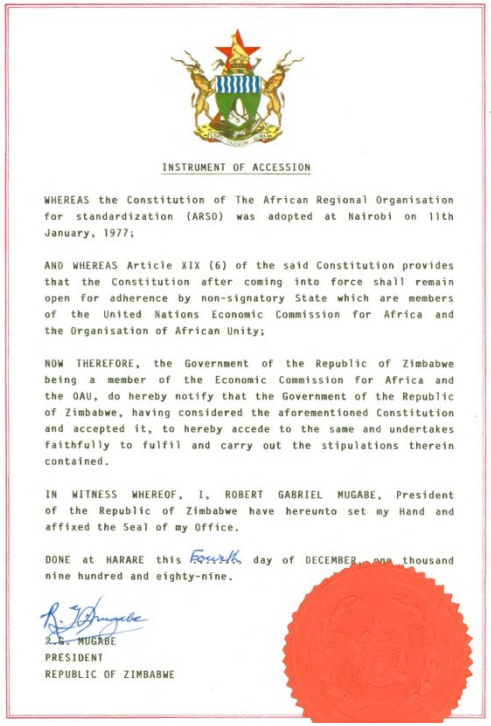
c. operate a regional certification marking scheme with a view to certifying the quality of and promoting African products;

d. encourage and facilitate the development by AU Member States of technical regulations to be based on African harmonised standards and/or international standards;

e. promote and facilitate exchange of experts, information and co-operation in training of personnel in standardisation activities;

f. create appropriate bodies in addition to the organs of the organization for the purposes of fulfilling its objectives.

ARSO: Intergovernmental Organization Established in 1977 by OAU (Currently AU) and UNECA



INSTRUMENT OF ACCESSION

WHEREAS the Constitution of The African Regional Organisation for standardization (ARSO) was adopted at Nairobi on 11th January, 1977;

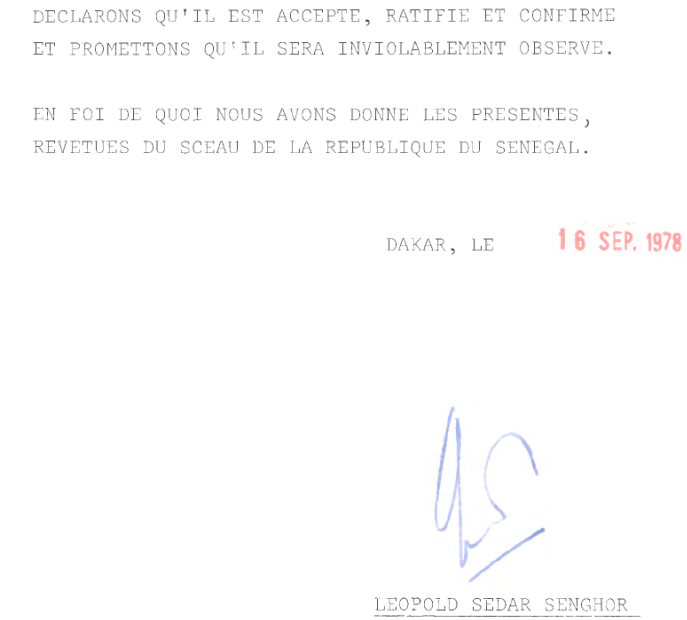
AND WHEREAS Article XIX (6) of the said Constitution provides that the Constitution after coming into force shall remain open for adherence by non-signatory State which are members of the United Nations Economic Commission for Africa and the Organisation of African Unity;

NOW THEREFORE, the Government of the Republic of Zimbabwe being a member of the Economic Commission for Africa and the OAU, do hereby notify that the Government of the Republic of Zimbabwe, having considered the aforementioned Constitution and accepted it, to hereby accede to the same and undertakes faithfully to fulfil and carry out the stipulations therein contained.

IN WITNESS WHEREOF, I, ROBERT GABRIEL MUGABE, President of the Republic of Zimbabwe have hereunto set my Hand and affixed the Seal of my Office.

DONE at HARARE this Fourth day of DECEMBER, one thousand nine hundred and eighty-nine.

R. G. MUGABE
PRESIDENT
REPUBLIC OF ZIMBABWE



DECLARONS QU'IL EST ACCEPTE, RATIFIE ET CONFIRME ET PROMETTONS QU'IL SERA INVIOLABLEMENT OBSERVE.

EN FOI DE QUOI NOUS AVONS DONNE LES PRESENTES, REVETUES DU SCEAU DE LA REPUBLIQUE DU SENEGAL.

DAKAR, LE 16 SEP. 1978

LEOPOLD SEDAR SENGHOR

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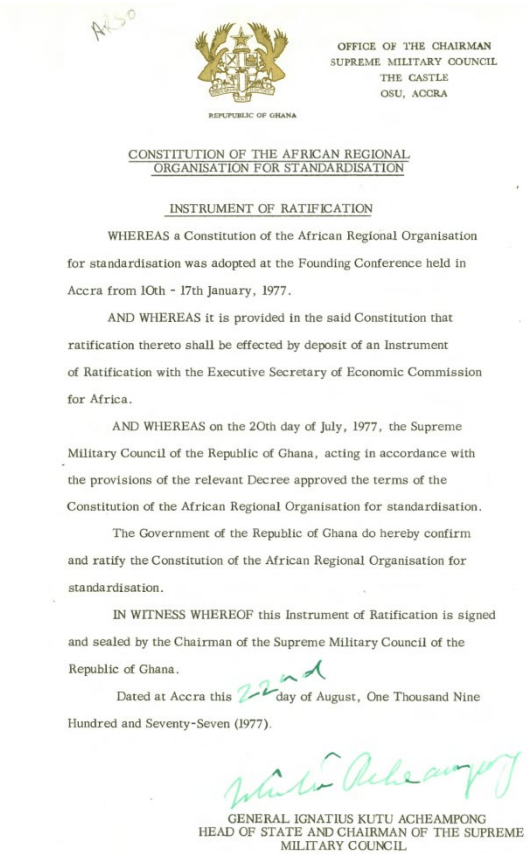


ARSO

OFFICE OF THE CHAIRMAN
SUPREME MILITARY COUNCIL
THE CASTLE
OSU, ACCRA

REPUPUBLIC OF GHANA

CONSTITUTION OF THE AFRICAN REGIONAL ORGANISATION FOR STANDARDISATION

INSTRUMENT OF RATIFICATION

WHEREAS a Constitution of the African Regional Organisation for standardisation was adopted at the Founding Conference held in Accra from 10th - 17th January, 1977.

AND WHEREAS it is provided in the said Constitution that ratification thereto shall be effected by deposit of an Instrument of Ratification with the Executive Secretary of Economic Commission for Africa.

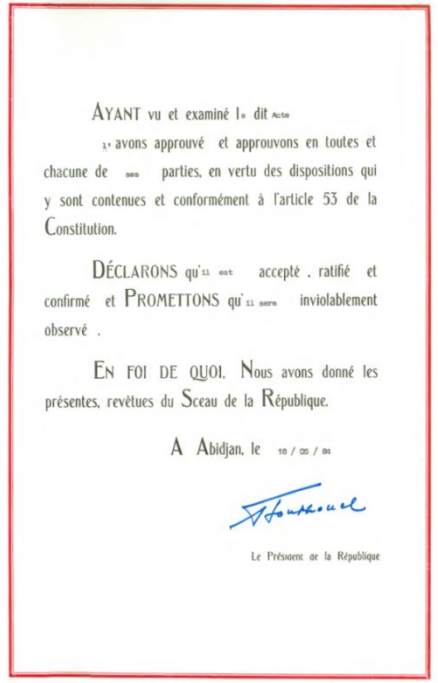
AND WHEREAS on the 20th day of July, 1977, the Supreme Military Council of the Republic of Ghana, acting in accordance with the provisions of the relevant Decree approved the terms of the Constitution of the African Regional Organisation for standardisation.

The Government of the Republic of Ghana do hereby confirm and ratify the Constitution of the African Regional Organisation for standardisation.

IN WITNESS WHEREOF this Instrument of Ratification is signed and sealed by the Chairman of the Supreme Military Council of the Republic of Ghana.

Dated at Accra this 22nd day of August, One Thousand Nine Hundred and Seventy-Seven (1977).

GENERAL IGNATIUS KUTU ACHEAMPONG
HEAD OF STATE AND CHAIRMAN OF THE SUPREME MILITARY COUNCIL



AYANT vu et examiné l… dit Acte … avons approuvé et approuvons en toutes et chacune de ses parties, en vertu des dispositions qui y sont contenues et conformément à l'article 53 de la Constitution.

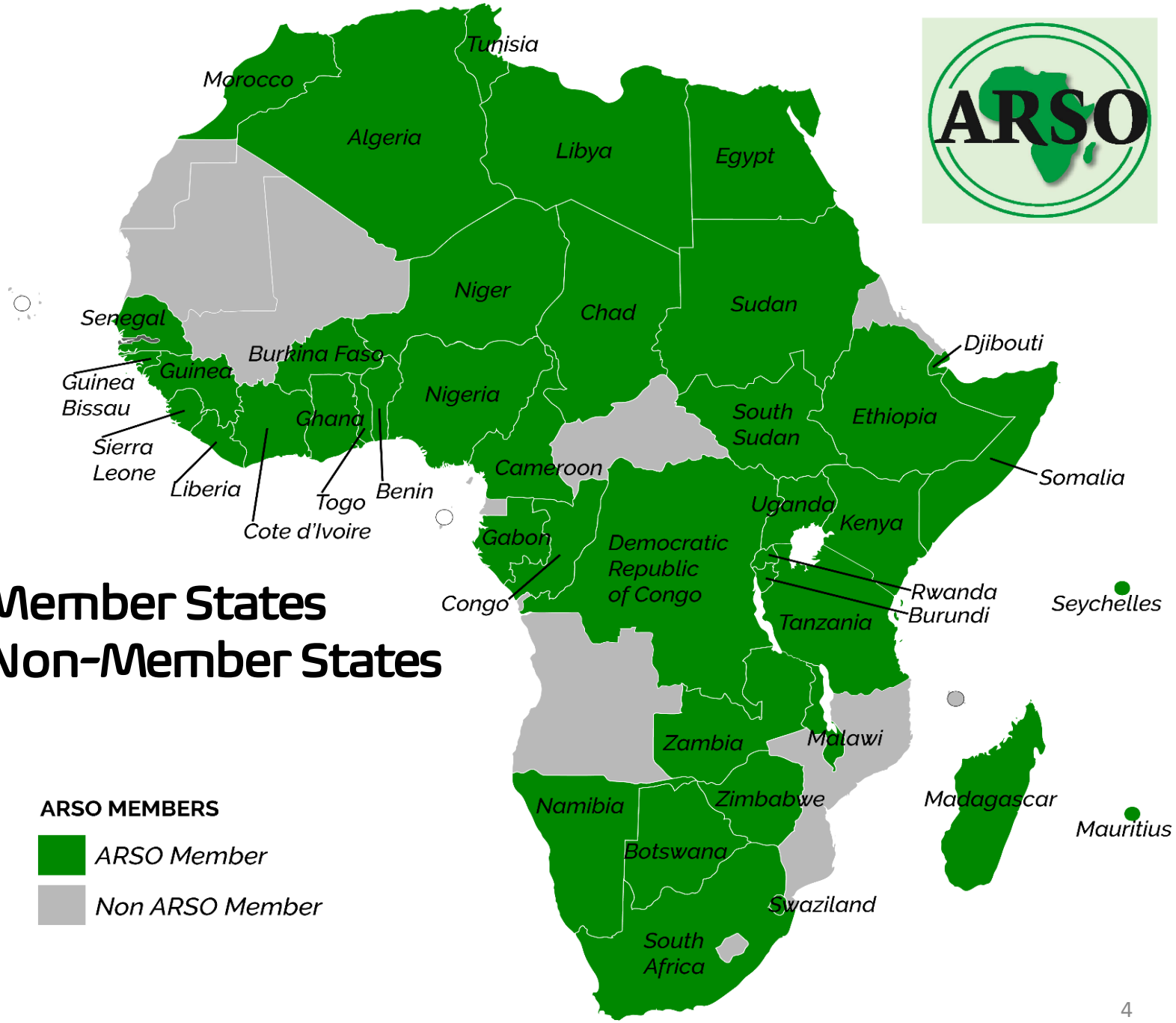
DÉCLARONS qu'il est accepté, ratifié et confirmé et PROMETTONS qu'il sera inviolablement observé.

EN FOI DE QUOI, Nous avons donné les présentes, revêtues du Sceau de la République.

A Abidjan, le 18 / 05 / 84

Le Président de la République

Current ARSO Membership



43 Member States
12 Non-Member States

ARSO Mission

State of the Pharmaceutical and Medical Devices Manufacturing in Africa (1)

- Africa bears a disproportionate burden of disease with about 75% of the world's people living with HIV/ AIDS and 90% of the deaths due to malaria while many people also suffer most from tuberculosis and there are many other infectious diseases that cause substantial morbidity and mortality as well as increasing problems of noncommunicable diseases
- Approximately 1.6 million Africans died of malaria, tuberculosis and HIV-related illnesses in 2015.
- These diseases can be prevented or treated with timely access to appropriate and affordable medicines, vaccines and other health services.
- But less than 2% of drugs consumed in Africa are produced on the continent, meaning that many sick patients do not have access to locally produced drugs and may not afford to buy the imported ones.

State of the Pharmaceutical and Medical Devices Manufacturing in Africa (2)

- The demand for safe, effective and affordable medicines is therefore great, but weak local pharmaceutical manufacturing capacity means that Africa largely depends on imported medicines.

- Many life-saving drugs are still inaccessible and unaffordable in low- and middle-income countries, particularly in Sub-Saharan Africa. This contributes to poor health outcomes, wider health and socioeconomic inequities, and higher patient spending on healthcare.

- Benefits of local production; (1) ensuring the quality of medicines, (2) avoiding stock outs, (3) supporting local incomes and jobs, (4) triggering technology spillovers, (5) addressing new challenges like non-communicable diseases, and (6) helping the sustainability of government medical schemes (UNIDO, 2015)

Does Africa Need to Manufacture Medical Devices?

- Medical devices are essential to the diagnosis and treatment of many diseases, particularly within surgical specialties, radiology, and critical care.
- A medical device is any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software, material, or related article used for a specific medical purpose.
- Most existing medical devices were built for the demands and resources available in high-income countries and are not adapted to the challenges often present in many countries in Africa.
- Most medical devices are designed by western firms from efficient innovation systems with a focus on their home markets. A disproportionately high percentage of imported medical devices in low resource settings become non-functional
- Therefore, there is an urgent need to develop medical devices that are specifically designed to address these challenges to improve African patients' access to medical care.

State of Production of Medical Devices in Africa

- In most African countries, more than 90% of the medical devices in public hospitals are imported, with very limited local production
- Moreover, most medical devices cannot be serviced and maintained locally, given the lack of local infrastructure
- There is limited local manufacturing capacity and design mechanism to incentivise manufacturers to engage in the production of priority medical devices
- Local medical device manufacturers not starting up due to the high capital investment required, the prohibitive and unaligned regulatory framework, brand representation and the unwillingness of end users to switch to smaller brands, and cash flow and liquidity problems
- MNCs' dominance in the medical device industry; lack of funding and incentives for manufacturers; high cost of regulatory compliance; import duties on components which are often higher than the price of finished goods; and unavailability and unreliability of raw materials from local suppliers

Regulatory Environment in Africa

- The regulation of medical devices is still developing in many African countries, where regulatory controls are not yet well established to prevent the importation or use of sub-standard devices
- The regulatory approval process for medical devices in Africa is lengthy, opaque, and skewed towards controlling entry into the market of substandard imports, which pose a risk to health
- The regulatory environment, or lack thereof, is a key issue for manufacturers in Africa. It should be considered an issue of vital importance to be addressed for the development of the medical devices sector
- The WHO encourages the harmonisation of medical device regulation towards standardisation, to promote uniformity between national medical device bodies. In an era of globalisation, this facilitates cooperation among regulators and the industry, particularly with regard to audits, submission requirements, use of international standards and exchange of safety information, and also leverages experience gained over time

Global Trade in Medical Devices and Equipment

- From 2001 to 2020, the global trade volume of medical devices increased rapidly from US$112.963 billion to US$488.256 billion, representing an average annual growth of 7.23%.
- Changes in total trade volume are the combined result of changes in participating economies and trade volumes.
- With the continuous expansion of the global trade of medical devices, the number of participants in the trade has been increasing, and the structure of the trade network has become increasingly complex.
- From 2001 to 2020, the number of participants in the global medical device trade increased from 190 to 230, and the number of trade connections increased from 5,434 to 5,640, representing an increase of 17.39.0% and 6.65%, respectively.

Top 10 net import and export countries from 1990 to 2020 (US$million)

	Net export countries		Net import countries	
Rank	Country	Trade value	Country	Trade value
1	Sweden	1,401.12	Russia	996.02
2	US	1,358.32	South Korea	647.10
3	UK	1,112.55	China	503.80
4	Israel	856.62	Brazil	338.80
5	Germany	585.23	Japan	314.41
6	Netherlands	375.96	India	291.63
7	Belgium	246.29	Turkey	177.30
8	France	155.17	Italy	158.66
9	Canada	149.55	Australia	146.31
10	Switzerland	112.43	Thailand	133.94

- *Import-dependent medical equipment and supplies market tops US$3.2 billion as African countries rely on imported medical equipment and supplies*

Harmonization of Standards for Medical Devices in Africa: Role

(1) Strategic selection of essential medicinal products for local production
(2) Pricing of locally produced products that governments and people could afford
(3) Strict compliance to quality and safety standards by the manufacturers
(4) Health security – an uninterrupted supply of essential medicines and medical devices
(5) Innovation for development of formulations that are suitable for local conditions
(6) Facilitation for development of medical products for diseases which are neglected at the international level but are of significant interest at national, sub-regional and continental levels
(7) Gaining competitiveness and recognition for international accreditation of local industries in the manufacture of medical products.
(8) Create the basis for harmonization of medicines regulations and mutual recognition of regulators to facilitate intra-African trade in pharmaceuticals and medical devices.
(9) Form the basis for governments to formulate public procurement contracts with producers.

Harmonization of Standards for Medical Devices in Africa: Genesis

(1) The ARSO harmonization project on harmonization of standards started as a response to the challenges faced by African countries during the Covid-19 pandemic

(2) There was need to fast-track development of standards to guide in the African countries to produce essential equipment and medicinal products…sanitizers, PPE, masks, gowns, ventilators/respirators

(3) There was need to develop protocols to handle patients safely

(4) There was need to establish guidelines on establishing emergency field hospitals with medical devices and equipment to handle influx of patients

(5) After the emergency period, it was decided to develop and harmonize standards for long-term needs of medical devices and equipment for hospitals.

ARSO/TC 78, Medical devices and equipment

Scope: Standardization in the following fields:

- Assistive products for persons with disability;
- Electrical equipment in medical practice;
- Transfusion, infusion and injection equipment for medical and pharmaceutical use;
- Devices for administration of medicinal products and intravascular catheters;
- Dentistry and oral hygiene products;
- Anaesthetic and respiratory equipment;
- Implants for surgery;
- Prosthetic and orthotics;
- Surgical instruments;
- Mechanical contraceptives;
- Quality management and corresponding general aspects for medical devices

Sample Standards Harmonized

(1) ARS GL 1740:2021, *Guidelines on the import & Export of Pharmaceuticals and Medical devices within the African countries. (Principles for regional coding of pharmaceutical products falsified products across the borders as part of the content)*

(2) ARS GL 1742:2021, *Guideline on good reliance practice in the regulation of medical products*

(3) ARS GL 1743:2021, *Guidelines on collaboration, collation and accessibility on database of medical devices manufacturers in Africa*

(4) ARS GL 1744:2021, *Guideline on the development of Summary technical documentation (STED) for demonstrating conformity to the essential principles of safety and performance of medical devices (STED)*

(5) ARS GL 1745:2021, *Guidance tool on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions*

(6) ARS GL 1746:2021, *Guidelines on pool procurement of pharmaceuticals and medical and in vitro devices in Africa*

(7) ARS GL 1747:2021, *Guideline on the development of summary technical documentation (STED) for demonstrating conformity to the essential principles of safety and performance of IVD (STED).*

Sample Standards Harmonized

(1) ISO 13485:2016, *Medical devices – Quality management systems — Requirements for regulatory purposes*
(2) ISO 14971:2019, *Medical devices — Application of risk management to medical devices*
(3) ISO 23907-1:2019, *Sharps injury protection — Requirements and test methods — Part 1: Single-use sharps containers*
(4) ISO 23907-2:2019, *Sharps injury protection — Requirements and test methods — Part 2: Reusable sharps containers*
(5) ISO 13688:2013, *Protective clothing — General requirements*
(6) ISO 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*
(7) ISO 7886-2:2020, *Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps*
(8) ISO 7886-3:2020, *Sterile hypodermic syringes for single use — Part 3: Auto disabled syringes for fixed dose immunization*
(9) ISO 7886-4:2018, *Sterile hypodermic syringes for single use — Part 4: Syringes with reuse prevention feature*

Thank you!

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