Medical Device Accelerated License for Production (Local Manufacturer) and Distribution During Covid 19 outbreak.

The Indonesian Ministry of Health has expedited the application process for the licenses required to produce domestically and distribute certain medical devices to deal with COVID-19. It has accelerated certification services for production and distribution certificates, and is offering one-day service for Marketing Authorization (*Izin Edar*) too.

The medical devices prioritized by the MOH:

The MoH announced on April 17th that manufacturers or distributors that wish to produce or distribute the above medical devices can obtain a production certificate or distribution certificate (IPAK) within one to two days and also the MoH simplified the required documents and information upon fulfilling:

1. Make sure the companies business identification (NIB) connected either OSS (Operation Support System) and MoH portal.
2. Submitting the required administrative documents.
3. The license approval will be one or two days after government fees payment.
4. Production certificate or Distribution certificate will have 1 year validity and can be extended afterward.

The MoH Relaxes Licensing Requirements to Obtain Marketing Authorization Using Accelerated Scheme

Especially for local manufacturers that have already obtained a production certificate can obtain the relevant Marketing Authorization in less than a week upon fulfilling the requirements as stipulated in the MOH's Technical Licensing Guidelines for Medical Devices and Household Supplies. While the MOH has cut the timeline for obtaining Marketing Authorization, it has not changed the required application documents, in order to ensure the quality of medical devices and household supplies distributed in Indonesia. In total, manufacturers should be able to start business operations in approximately one to two weeks.

To accelerate the issuance of production and distribution certificates the MOH is providing services every day from 8 am to 4 pm, Monday to Friday, and from 8 am to noon on Saturdays and Sundays. For the one-day service for Marketing Authorization, the MOH is providing services 24 hours a day, seven days a week until June 30, 2020.

List of products that are expected to be produced in Indonesia:

1. Surgical Mask
2. Surgical Gloves
3. Coverall
4. Hand Sanitizer
5. Ventilator
6. Resuscitator
7. CPAP (Continous Positive Airway Perssure)
8. High Flow Nasal Cannula

Licensing Exemption for Importation and Distribution of Certain Medical Devices

Under new rules issued by the ministry of health No HK.01.07/MENKES/218/2020 dated March 30, the importation of certain medical devices no longer requires import license refers to certain of HS code (Harmonization standard code) listed on the rules.

The importers will only be required to obtain a recommendation from the National Disaster Management Agency (BNPB / Badan Nasional Penanggulangan Bencana) which they can apply for through the Indonesia National Single Window online system (http://insw.go.id) . The list of HS Codes for medical devices eligible for the licensing exemption is contained in MOH Decree No. HK.01.07/MENKES/218/2020. These exemptions will apply until June 30, 2020.

Hs Code lists:

DAFTAR ALAT KESEHATAN, ALAT KESEHATAN DIAGNOSTIK *IN VITRO*, DAN PERBEKALAN KESEHATAN RUMAH TANGGA YANG DIKECUALIKAN DARI PERIZINAN TATA NAGA IMPOR DALAM RANGKA PENANGGULANGAN *CORONA VIRUS DISEASE* 2019 (COVID-19)

NO	POS TARIF (HS CODE)	URAIAN BARANG
1	3004.90.30	- - Antiseptik
2	3808.94.10	- - - Mengandung campuran dari asam ter batu bara dan alkali
3	3808.94.20	- - - Lain-lain, dalam kemasan aerosol
4	3808.94.90	- - - Lain-lain
5	3401.30.00	- Produk dan preparat aktif-permukaan organik untuk membersihkan kulit, dalam bentuk cair atau krim dan disiapkan untuk penjualan eceran, mengandung sabun maupun tidak
6	3821.00.10	- Media kultur olahan untuk pengembangan mikro organisme
7	3822.00.10	- Pelat, lembaran, film, foil dan strip dari plastik diresapi atau dilapisi reagen diagnosa atau laboratorium
8	3822.00.20	- Kertas karton, gumpalan selulosa dan jaringan dari serat selulosa diresapi atau dilapisi reagen

NO	POS TARIF (HS CODE)	URAIAN BARANG
		diagnosa atau laboratorium
9	3822.00.90	- Lain-lain
10	3926.90.99	- - - Lain-lain
11	4015.11.00	- - Untuk bedah
12	4015.19.00	- - Lain-lain
13	6211.43.10	- - - Pakaian bedah
14	6307.90.40	- - Masker bedah
15	9018.31.10	- - - Alat suntik sekali pakai
16	9018.31.90	- - - Lain-lain
17	9018.90.30	- - Instrumen dan peralatan elektronik
18	9018.90.90	- - Lain-lain
19	9019.20.00	- Aparatus terapi ozon, terapi oksigen, terapi aerosol, nafas buatan atau aparatus pernafasan terapeutik lainnya
20	9020.00.00	Peralatan nafas dan masker gas lainnya, tidak termasuk masker pelindung yang tidak mempunyai bagian mekanis maupun filter yang dapat diganti.
21	9022.14.00	- - Lain-lain, untuk keperluan medis, pembedahan atau kedokteran hewan
22	9027.80.30	- - Lain-lain, dioperasikan secara elektrik