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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

අංක 2295/18 - 2022 සැප්තැම්බර් මස 01 වැනි බ්‍රහස්පතින්දා - 2022.09.01
No. 2295/18 - THURSDAY, SEPTEMBER 01, 2022

(Published by Authority)

PART I : SECTION (I) — GENERAL

Government Notifications

L.D.B. 9/2016 (III)

THE NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015

REGULATIONS made by the Minister of Health under Section 142 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

DR. KEHELIYA RAMBUKWELLA,
Minister of Health.

Colombo,
31st of August, 2022.



Regulations

The Medical Devices Pricing Regulations, No. 01 of 2017 published in the *Gazette* Extraordinary No. 2006/45 of February 17, 2017, as amended by regulations published in *Gazette* Extraordinary No. 2114/54 of March 15, 2019 as amended by regulations published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 and by regulations published in the *Gazette* Extraordinary No. 2273/04 of March 28, 2022 are hereby further amended as follows: -

(1) by the repeal of sub regulation (2) of regulation 3 thereof, and the substitution therefor, of the following: -

“(2) On the date of publication of these regulations, a manufacturer or importer who sells any Medical devices at a revised retail price under the Medical Devices Pricing Regulations No. 01 of 2017 published in the *Gazette* Extraordinary No. 2006/45 of February 17, 2017 as amended by regulations published in *Gazette* Extraordinary No. 2114/54 of March 15, 2019 as amended by regulations published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 as amended by regulations published in the *Gazette* Extraordinary No. 2273/04 of March 28, 2022 which is less than the maximum retail price specified in Column IV of the Schedule to the Medical Devices Pricing Regulations No. 01 of 2017 published in *Gazette* Extraordinary No. 2006/45 of February 17, 2017 as amended may increase proportionately such revised retail price by a total forty *per centum* (40%).”

(2) by the repeal of the Schedule and the substitution therefor, of the following: -

SCHEDULE

(Regulation 2)

INTRAOCULAR LENSES/LENSES WITH DELIVERY SYSTEM (PRELOADED/PROVIDED WITH CARTRIDGE)

<i>Column I</i>	<i>Column II</i>	<i>Column III</i>	<i>Column IV</i>
	Brand Name /Approved Name	Manufacturer	Maximum Retail Price MRP (SLR)
1.	AcrySert Preloaded delivery system	Alcon	Rs. 38,287.20
2.	AcrySof IQ SN60WF with cartridge	Alcon	Rs. 36,929.81
3.	Tecnis 1 piece	Abbot Medical	Rs. 36,477.05
4.	enVista	Bausch & Lomb	Rs. 34,902.21
5.	Tecnis monofocal	Abbot Medical	Rs. 34,902.21
6.	Hoya iSert 251	Hoya	Rs. 27,264.28
7.	Nidek Nex-Load system SP SZ-1	Nidek	Rs. 27,264.28
8.	Aqua Sense Aaris	Aaren Scientific	Rs. 22,067.33
9.	Bi-flex HB (877FABY standard IOL)	Medicentur	Rs. 20,079.11

<i>Column I</i>	<i>Column II</i>	<i>Column III</i>	<i>Column IV</i>
10.	Bunny HP	Hanita Marketing	Rs. 19,586.97
11.	I-Stream preloaded	MD Tech	Rs. 16,663.69
12.	Aurovue EV	Aurolab	Rs. 11,151.78
13.	AcrySof SP SA60AT with cartridge	Alcon	Rs. 29,528.10
14.	AcrySof EXPAND MA60MA with cartridge	Alcon	Rs. 29,528.10
15.	Sensar 1 piece	Abbot Medical	Rs. 28,829.18
16.	Sensar	Abbot Medical	Rs. 26,476.86
17.	AcrySof MP MA60AC	Alcon	Rs. 24,094.93
18.	Hoya PY60R	Hoya	Rs. 17,795.60
19.	Acriva UD (blue filter)	VSYS Biotech	Rs. 15,551.44
20.	Supra Phob Preloaded system	Appasamy	Rs. 14,645.94
21.	Acriva UD	VSYS Biotech	Rs. 14,764.05
22.	Akreos - MI60	Bausch & Lomb	Rs. 33,337.22
23.	Akeros AO	Bausch & Lomb	Rs. 26,122.53
24.	Akreos Adapt	Bausch & Lomb	Rs. 24,409.90
25.	Bunny AFM	Hanita Marketing	Rs. 23,917.76
26.	CT Asphina 404	Carl Zeiss Meditec	Rs. 23,622.48
27.	CT Spheris 204	Carl Zeiss Meditec	Rs. 18,464.91
28.	Bunny AF	Hanita Marketing	Rs. 16,220.77
29.	C-Flex Aspheric 970C/920H	Rayner	Rs. 13,582.93
30.	Aspira-aAY	Human Optics	Rs. 12,834.88

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I කොටස : (I) ඡේදය - ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ අති විශේෂ ගැසට් පත්‍රය - 2022.09.01
PART I : SEC. (I) - GAZETTE EXTRAORDINARY OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA - 01.09.2022

<i>Column I</i>	<i>Column II</i>	<i>Column III</i>	<i>Column IV</i>
31.	Ocuva	VSY Biotech	Rs. 9,015.91
32.	Auroflex	Aurolab	Rs. 4,055.19
33.	Seelens	Hanita Marketing	Rs. 13,966.79
34.	C-Flex IOL (Spherical 570C)	Rayner	Rs. 11,515.96
35.	Aspira AS	Human Optics	Rs. 11,712.81
36.	Tecsoft Tetra	Fred Hollows	Rs. 10,826.97
37.	Tecsoft Flex	Fred Hollows	Rs. 10,137.98
38.	Acryfold	Appasamy	Rs. 6,889.89

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L.D.B. 9/2016 (III)

THE NATIONAL MEDICINES REGULATORY AUTHORITY ACT, NO. 5 OF 2015

REGULATIONS made by the Minister of Health under Section 142 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

DR. KEHELIYA RAMBUKWELLA,
Minister of Health.

Colombo,
31st of August, 2022.

Regulations

The Medical Devices Pricing Regulations, No. 05 of 2017, published in the *Gazette* Extraordinary No. 2030/47 of August 04, 2017, as amended by regulations published in *Gazette* Extraordinary No. 2114/54 of March 15, 2019 as amended by regulations published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 and by regulations published in *Gazette* Extraordinary No. 2273/04 of March 28, 2022 are hereby further amended as follows : -

(1) by the repeal of sub regulation (2) of regulation 3 thereof and the substitution therefor, of the following: -

“(2) On the date of publication of these regulations, a manufacturer or importer who sells any Medical devices at a revised retail price under the Medical Devices (Pricing) Regulations, No. 05 of 2017, published in *Gazette* Extraordinary No. 2030/47 of August 04, 2017 as amended by regulations published in *Gazette* Extraordinary No.2114/54 of March 15, 2019 as amended by *regulations* published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 and by regulations published in *Gazette* Extraordinary No. 2273/04 of March 28, 2022 which is less than the maximum retail price specified in Column II of the Schedule to the Medical Devices (Pricing) Regulations, No. 05 of 2017, published in *Gazette* Extraordinary No. 2030/47 of August 04, 2017as amended may increase proportionately such revised retail price by a total forty *per centum* (40%).”

(2) by the repeal of the Schedule and the substitution therefor, of the following: -

SCHEDULE

(Regulation 2)

No.	Column I	Column II
	Item	Maximum Retail Price (MRP) (SLR)
1.	Bare Metal Stent	Rs. 54,036.42
2.	Drug Eluting Stent	Rs. 236,224.80

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L.D.B. 9/2016 (III)

THE NATIONAL MEDICINES REGULATORY AUTHORITY ACT, NO. 5 OF 2015

REGULATIONS made by the Minister of Health under Section 142 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

DR. KEHELIYA RAMBUKWELLA,
Minister of Health.

Colombo,
31st of August, 2022.

Regulations

The Medical Devices (Pricing) Regulations, 2018 published in the *Gazette* Extraordinary No. 2086/37 of August 31, 2018, as amended by regulations published in *Gazette* Extraordinary No. 2114/54 of March 15, 2019 as amended by regulations published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 and by regulations published in the *Gazette* Extraordinary No. 2273/04 of March 28, 2022 are hereby further amended as follows: -

(1) by the repeal of sub regulation (2) of regulation 3 thereof and the substitution therefor, of the following: -

“(2) On the date of publication of these regulations, a manufacturer or importer who sells any Medical devices at a revised retail price under the Medical Devices (Pricing) Regulations, 2018 published in the *Gazette* Extraordinary No. 2086/37 of August 31, 2018, as amended by regulations published in *Gazette* Extraordinary No. 2114/54 of March 15, 2019 as amended by regulations published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 and by regulations published in the *Gazette* Extraordinary No. 2273/04 of March 28, 2022 which is less than the maximum retail price specified in Column II of the Schedule to the Medical Devices (Pricing) Regulations, 2018 published in the *Gazette* Extraordinary No. 2086/37 of August 31, 2018, as amended may increase proportionately such revised retail price by a total Forty *per centum* (40%).”

(2) by the repeal of the Schedule and the substitution therefor of the following:-

SCHEDULE

(Regulation 2)

MAXIMUM RETAIL PRICES OF TWO SELECTED MEDICAL DEVICES

No.	Column I	Column II
	Approved Name	Maximum Retail Price (MRP) (SLR)
1.	BLOOD GLUCOSE MONITORING SYSTEM	6,200.90 Per Unit
2.	TEST STRIPS FOR BLOOD GLUCOSE MONITORING SYSTEM	112.21 Per Strip

L.D.B. 9/2016 (III)

THE NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015

REGULATIONS made by the Minister of Health under Section 142 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

DR. KEHELIYA RAMBUKWELLA,
Minister of Health.

Colombo,
31st of August, 2022.

Regulations

The Medical (Pricing of Medical Devices) Regulations No. 1 of 2021 published in the *Gazette* Extraordinary No. 2243/20 of September 04, 2021 as amended by regulations published in the *Gazette* Extraordinary No. 2273/04 of March 28, 2022 is hereby further amended as follows :-

(1) by the repeal of sub regulation (4) of regulation 2 thereof and the substitution therefor, of the following: -

“(4) On the date of publication of these regulations, a manufacturer or importer who sells any Medical device at a revised retail price under the Medical (Pricing of Medical Devices) Regulations No. 1 of 2021 published in the *Gazette* Extraordinary No. 2243/20 of September 04, 2021 as amended by regulations published in the *Gazette* Extraordinary No. 2273/04 of March 28, 2022 which is less than the maximum retail price specified in Column II of the Schedule to the Medical (Pricing of Medical Devices) Regulations No. 1 of 2021 published in the *Gazette* Extraordinary No. 2243/20 of September 04, 2021 as amended may increase proportionately such revised retail price by a total forty *per centum* (40%).”

(2) by the repeal of the Schedule and the substitution therefor of the following :-

SCHEDULE

(Regulation 2)

MAXIMUM RETAIL PRICE OF SELECTED MEDICAL DEVICE

No.	Column I	Column II
	Approved Name	Maximum Retail Price per unit (MRP) (SLR)
1.	Pulse Oximeter	Rs. 5,418.00

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