



RWANDA FDA
Rwanda Food and Drugs Authority

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Kigali, 16th May 2020

Ref N^o: ODG/CRC/009/Rwanda FDA/2020

TO: ALL MANUFACTURERS OF BARRIER MASKS

Subject: Addendum to the guidance N^o: DIS/GDC/001 on manufacturing and use of Barrier Masks

Reference is made to the Guidance N^o: DIS/GDC/001 on manufacturing and use of Barrier Masks with effective date of 17th April 2020 where clause 4.2 on requirement of dimensions of barrier masks specifies that it shall be sized in such a way as to correspond to the average morphology of the target Rwandan population, the proposed dimensions are based on certain anthropomorphic data in ISO/TS 16976-2:2015 Respiratory protective devices - Human factors - Part 2: Anthropometrics;

Rwanda FDA has so far received many complaints on sizes of barrier masks proving that the above mentioned requirement is not taken into consideration by most of companies that were approved to manufacture barrier masks. It is on the above background that the following information is provided as an addendum to the **Guidance N^o: DIS/GDC/001** and the labelling of each single package of barrier masks must show in addition to the requirements of clause 9 of the guidance No: DIS/GDC/001, the size or age group in accordance with the table below.

Dimensions for reusable barrier masks

Characteristic	Young Children (2-4 years)	Children (4-12 years)	Teens, Adults
Width, mm, min.	150	170	180
Depth, mm, min.	80	120	160

Rwanda FDA takes this opportunity to remind you again that the head harness shall be designed such that the barrier mask can be easily put on and removed. It shall be sufficiently

robust to hold the barrier mask in place in such a way as to avoid excessive tightness and discomfort when worn as specified in guidance No: DIS/GDC/001 on manufacturing and use of Barrier Masks

Thanking you for your continued good collaboration.

Dr. Charles KARANGWA
Ag. Director General

