

Temporary Compliance Waiver Notice

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Philip Morris Products S.A.	Confidential
<i>IQOS</i> 3 System Holder and Charger - MRTPA	Page 1 of 1
5 – Environmental Impact Assessment	Version 1.0

Module 5: Environmental Impact Assessment

PMP S.A. is not providing any new information or data in the context of this supplemental MRTPA for the *IQOS* 3 System Holder and Charger.

The issuance of a Modified Risk Granted Order – Exposure Modification for the *IQOS* 3 System Holder and Charger is not expected to affect the estimates of the first- and fifth-year market volumes in the United States for the *IQOS* 3 and the *IQOS* 2.4 device (Holder + Charger) as presented in the supplemental PMTA for the *IQOS* 3 System Holder and Charger (PM0000133).

Therefore, information concerning the environmental impact that may result from introduction on the U.S. market of the *IQOS* 3 System Holder and Charger supplied with the supplemental PMTA for that product, as an Addendum to the EIA, and subsequent amendment¹, remains valid and does not require reanalysis. Thus, Module 5 of the supplemental PMTA for the *IQOS* 3 System Holder and Charger is cross-referenced in the context of this supplemental MRTPA.

¹ PMP S.A.'s August 27, 2020 written response to the FDA's Deficiency Letter of August 13, 2020, pertaining to the sPMTA for *IQOS* 3 System Holder and Charger (PM0000634).

Confidentiality Statement

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