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## **Module 3: Product Description**

## 3.2 Summary of Manufacturing

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.

Scientific evidence and information concerning manufacturers and manufacturing process supplied with the supplemental PMTA for the *IQOS* 3 System Holder and Charger (PM0000634), and subsequent amendment<sup>1</sup>, remains valid and do not require reanalysis. Therefore, the following Sections of the sPMTA for the *IQOS* 3 System, with related appendices and data, are cross-referenced in this application:

- 3.3.1 Manufacturers
- 3.3.2 Manufacturing Process
- 3.3.3 SOPs

## **Confidentiality Statement**

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris International.

<sup>&</sup>lt;sup>1</sup> 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).