Temporary Compliance Waiver Notice

The linked files may not be fully accessible to readers using assistive technology. We regret any inconvenience that this may cause our readers. In the event you are unable to read the documents or portions thereof, please email AskCTP@fda.hhs.gov or call 1-877-287-1373.

PHILIP MORRIS
PRODUCTS S.A.

Received
APR 01 2020
CTP Mailroom

RECEIVED
APR 01 2020
BY: CTP / DCC

March 30, 2020

CONFIDENTIAL
30 MAR 2020
COPY

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Supplementary PMTA for *IQOS* 3 System Holder and Charger, dated March 30, 2020 - Virus-Free Confirmation

Dear Sir or Madam,

The above-mentioned supplementary PMTA submission package is submitted on a 64 GB USB key, with serial number BN191157543Z.
The size of the submission is 1.62 GB.

The submission was scanned and certified as virus-free using the Windows Defender Security Center from Windows 10, virus/spyware definition version 1.313.378.0. The definition was last updated on March 20, 2020.

Sincerely,

(b) (6)

Marco Esposito
Director Product Stewardship
Philip Morris Products S.A.

PHILIP MORRIS
PRODUCTS S.A.

RECEIVED
APR 01 2020
BY: CTP / DCC

Received
APR 01 2020
CTP Mailroom

March 30, 2020

CONFIDENTIAL
30 MAR 2020
COPY

Dr. Matthew Holman
Director, Office of Science
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via electronic media

Subject: Premarket Tobacco Product Application (PMTA) for modified version of the authorized *IQOS* System Holder and Charger (PM0000479)

Dear Dr. Holman,

Philip Morris Products S.A. (PMP S.A.) is submitting this PMTA in accordance with requirements of Section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and requesting a marketing order under Section 910(c)(1)(A)(i) of the FD&C Act for the *IQOS* 3 System, which is a modified version of the *IQOS* System Holder and Charger, as authorized by Marketing Order of April 30, 2019, (PM0000479) (the "Authorized *IQOS* System").

This application is submitted as supplemental PMTA (sPMTA) in accordance with the advice received from FDA in the December 18, 2019, written response to the PMP S.A.'s pre-submission meeting request related to the planned submission of a PMTA under section 910(b) of the FD&C Act for *IQOS* 3 System. The Agency concluded that a sPMTA submission would be appropriate as the *IQOS* 3 System requires only limited information or revisions to the *IQOS* PMTA which was the subject of the Marketing Order[1].

The *IQOS* 3 System, which is the subject of this application, is to be used with any of the authorized Tobacco Stick variants, Marlboro *HeatSticks* (PM0000424), Marlboro Smooth Menthol *HeatSticks* (PM0000425) and Marlboro Fresh Menthol *HeatSticks* (PM0000426), the same as the Authorized *IQOS* System (PM0000479).

[1] FDA's written response of December 18, 2019 (STN: TC0005319) to the PMP S.A.'s October 11, 2019 meeting request related to the planned submission of a PMTA under section 910(b) of the FD&C Act for *IQOS* 3.

Upon issuance of an marketing order for the *IQOS* 3 System, Altria Client Services LLC (ALCS)[2] and an ALCS affiliate will be licensed to distribute and sell the product in the United States, the same as with the Authorized *IQOS* System (PM0000479). The ALCS affiliate that will distribute and sell the product in the United States is Philip Morris USA Inc. (PM USA)[3].

Detailed information regarding this application is provided in Module 1, Section 1.2 *General Information.*

This application is being submitted on electronic media, along with confirmation that it is virus-free.

PMP S.A. appreciates FDA's consideration of this application and looks forward to working with the Agency to secure a marketing authorization order under Section 910(c)(1)(A)(i) for the upgraded modified version of the *IQOS* System Holder and Charger discussed herein.

Sincerely,

(b) (6)

Daniel Verstappen
Vice President Regulatory, Quality & Standards
Philip Morris Products S.A.

(b) (6)

Jeffrey Walker, M.D.
U.S. Agent for PMP S.A.
CEO, Teton Regulatory Sciences

Please note that this submission contains confidential commercially sensitive, and/or trade secret information, and the legal protections provided to such information are hereby claimed under the applicable provisions of Unites States law. PMPSA understands that FDA will hold this documentation confidential and will refrain from the public disclosure of the information contained in this submission in conformity with such provisions of the law.

[2] PMP S.A.'s parent company, Philip Morris International Management S.A., has entered into a distribution agreement with Altria Client Services LLC

[3] PM USA is not part of Philip Morris International group of companies.

PHILIP MORRIS
PRODUCTS S.A.

Enclosures
Appendix A – Enclosures:

(1) USB stick containing PMP S.A.'s supplemental PMTA for for *IQOS* 3 System, an upgraded modified version of the *IQOS* System Holder and Charger

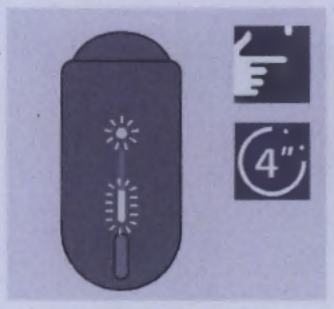
(2) Virus-scan confirmation

(3) Printed Labeling Specimens

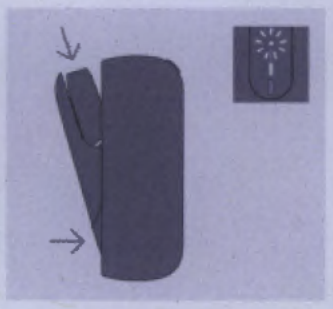
QUAI JEANRENAUD 3 CH-2000 NEUCHATEL SWITZERLAND TELEPHONE (41-58) 242 21 13 TELEFAX (41-58) 242 28 11

PAGE 1

How to use your IQOS®

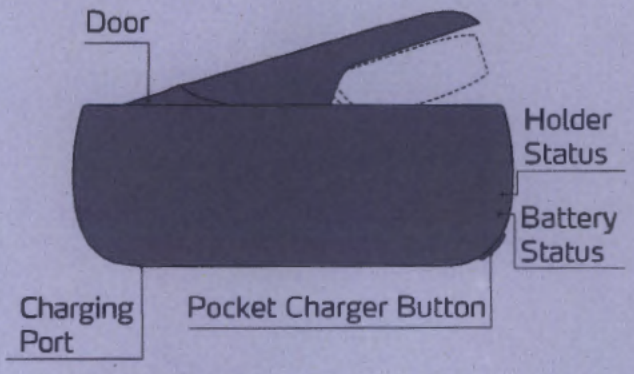


1. TURN ON
Press and hold IQOS® Pocket Charger Button for 4 seconds, then release; Holder Status and Battery Status lights will flash.

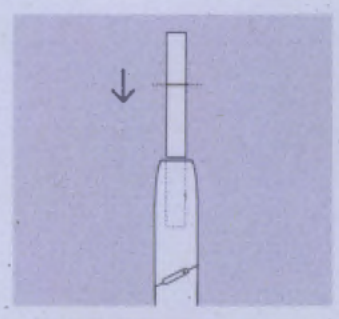


2. CHARGE HOLDER
Insert IQOS® Holder then close to charge. Fully charged when Holder Status light is solid white.

IQOS® 3 Pocket Charger



PAGE 2

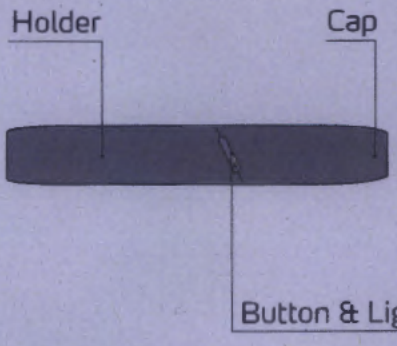


3. INSERT MARLBORO HEATSTICK
Insert and gently press the HeatStick tobacco-side down to the line on the filter.



4. START HEATING
Hold Holder Button until IQOS® Holder vibrates and Light pulses white.

IQOS® 3 Holder



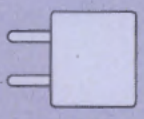
PAGE 3



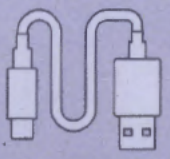
5. BEGIN USE
Start using once IQOS® Holder vibrates twice and Light is solid white.



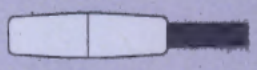
6. NEARLY COMPLETE
To signal the last 30 seconds, IQOS® Holder will vibrate twice and Light pulses white.



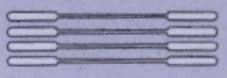
Power Adapter



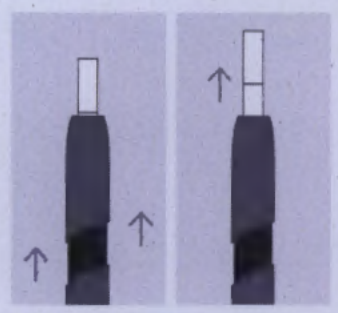
Charging Cable



IQOS® Cleaning Tool



IQOS® Cleaning Sticks



7. REMOVE HEATSTICK
Slide Cap upward, remove used HeatStick then slide cap back again. Insert the Holder back in the Pocket Charger to recharge.

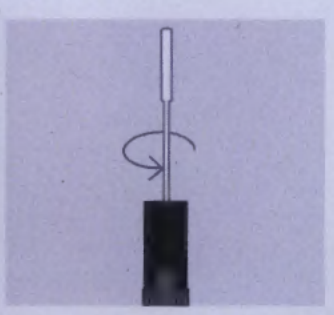
How to clean Holder



TO CLEAN
Slide Cap upward and remove completely. Insert IQOS® Cleaning Tool and rotate gently. Clean daily for optimal experience.

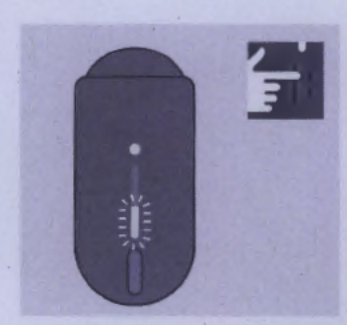
ENGAGE WITH IQOS®

For the full user guide and Customer Care support visit www.getIQOS.com

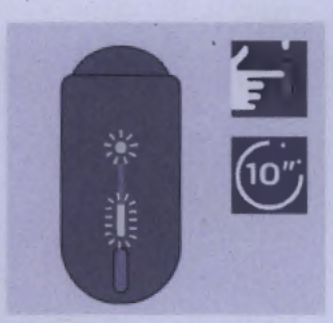


USE IQOS® CLEANING STICK
Insert IQOS® cleaning stick to wipe inside of the Holder. Do not touch the blade with the IQOS® Cleaning Stick.

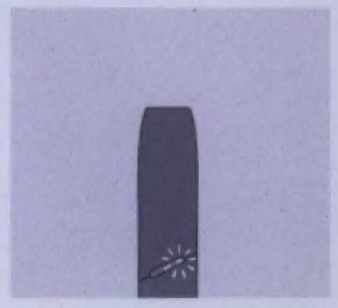
Quick Tips



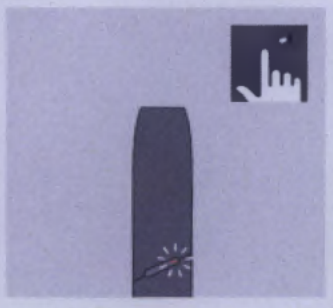
TO CHECK BATTERY STATUS
Tap IQOS® Pocket Charger Button to check battery level.



TO RESET
Press and hold IQOS® Pocket Charger Button for 10 seconds, then release; Battery Status light will fade in, flash twice, then progressively fade in to confirm a reset.



LIGHT FLASHES WHITE TWICE
IQOS® is outside operating temperature (<32°F/>122°F). Wait until device is within temperature limits.



LIGHT FLASHES RED
Reset IQOS®. If flashing persists, please contact Customer Care.

49.H990

IQOS®

This symbol indicates that caution is required when operating the product.

ENGLISH

SAFETY WARNINGS AND INSTRUCTIONS

PLEASE READ AND KEEP THESE INSTRUCTIONS

The Safety Warnings and Instructions included in this document cannot cover all the possible conditions and situations which could occur. Caution and care must be exercised when using or maintaining any personal electronic product. Only charge this product indoors. Only charge your product by using an approved IQOS® Power Adapter. Do not drop this product or subject it to strong shock. Keep away from children at all times and ensure that they do not play with this product. This product is not intended for use by persons with reduced physical, sensory or mental capabilities or lack of knowledge, unless they have been given supervision or instruction to use the product in a safe way and understand the hazards involved.

PAGE 2

Do not use this product under the following circumstances:.

- Where the use of electronic devices is prohibited.
- On or near heat sources, i.e. radiators or fires.
- If it is damaged, tampered with or broken.
- If it has been exposed to excessive heat or moisture.
- If the IQOS® Holder's cap is removed.
- If it becomes wet or is immersed in any liquid (this does not apply to the IQOS® Holder cap).
- If its batteries appear to be leaking. If the liquid comes in contact with the skin or eyes, wash with large amounts of water and seek medical advice.
- If it is operating in an erratic manner.
- If the battery in the Holder or Pocket Charger is unusually hot to the touch.

To reduce the risk of injury, always use this product in accordance with the manufacturer's instructions and follow these precautions:

- Do not touch this product if it becomes wet or immersed in any liquid.
- Never attempt to touch the Heater Blade.
- Do not attempt to open, modify or repair any component of this product or to replace any of the components or batteries. This product contains no user-serviceable parts.
- Never use this product in places where flammable materials, liquids and gases are present.

ATTENTION

IQOS® works exclusively with Marlboro HeatSticks®. Never use IQOS® with a conventional cigarette or similar products, or with tobacco sticks or accessories not approved by the manufacturer. Do not remove a HeatStick while in use. Marlboro HeatSticks® are single use only and should never be re-used. lit with a match, lighter or any other flame source.

49.H991 – IQOS 3 US Safety Warning Instructions_FOR FDA SUBMISSION ONLY

PAGE 3

⚠ IMPORTANT SAFETY INFORMATION

⚠ WARNING **Battery Risk**

IQOS® is powered by sealed Lithium-ion (Li-Ion) batteries. Under normal conditions of use, the battery is sealed. If battery fluid leaks, follow these precautions:

- If you swallow the fluid, seek medical attention immediately. Do not induce vomiting or ingest food or drink.
- If the fluid is inhaled, get fresh air and seek medical attention.
- In case of contact with skin, wash hands and do not touch eyes.
- In case of contact with eyes, immediately flush with running water for at least 15 minutes and seek medical attention.
- Only use the IQOS® USB Power Adapter for charging the IQOS® Pocket Charger
- Do not attempt to touch the IQOS® USB Power Adapter if it is wet.

⚠ CAUTION **Hot Aerosol Risk**

- When using IQOS® under hot and humid weather conditions, the water in the aerosol makes the aerosol temperature feel very hot.
- To help avoid this sensation, store your Marlboro HeatSticks® in a cool, dry place. Do not expose the product to high humidity conditions or direct sunlight. Do not use IQOS® during hot conditions or in periods of high humidity.
- If you experience discomfort, stop using the product and seek medical attention.

For any questions or concerns, please contact your local Customer Care (1-877-438-4767).
For more information please go to www.GetIQOS.com

INFORMATION FOR DISPOSING OF IQOS® 3



This symbol on the product or on its packaging indicates that this product and its individual parts (including batteries) must not be disposed of with your other household waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment.

Your IQOS® Device contains a Lithium-ion rechargeable battery. When discarded, it must be recycled or disposed of properly in accordance with state and local requirements. Do not crush the battery (e.g., such as in a trash compactor). Do not dispose of any part of this product in fire or flame. For further information on recycling and disposal of the battery call 1-877-2-RECYCLE (1-877-273-2925) or contact your local waste management officials.

49.H991 – IQOS 3 US Safety Warning Instructions_FOR FDA SUBMISSION ONLY

PAGE 4

Supplier's Declaration of Conformity – 47 CFR § 2.1077 Compliance Information

FCC Compliance Statement

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception (a) when charging, which can be determined by disconnecting and then reconnecting the device to the charging source, or (b) when in use, which can be determined by drawing on and ceasing to draw on the device, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- If the equipment is connected to the charger, then connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Cease to use (i.e., cease drawing on) the device.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Use only for intended purposes.

Unique Identifiers - A1404 and A1504

Responsible Party – U.S. Contact Information
Philip Morris USA
1-877-GET-IQOS (1-877-438-4767)
http://www.GetIQOS.com

TECHNICAL DATA

IQOS® 3 Holder Model: A1404
Battery type: Li-ion rechargeable battery
Input: 5V ⎓ 1.6A

IQOS® AC Power Adapter
Model: S52A21, S21A20, S21A22, S21A23, S21A25, S21A27,S21A27
Input: 100V-240V~ 50/60HZ 0.3A
Output: 5V ⎓ 2A

Micro USB Type C Cable

IQOS® 3 Pocket Charger
Model: M0002
Battery type: Li-ion rechargeable battery
Input: 5V ⎓ 2A

49.H991

49.H992 – IQOS 3 US Warranty Card_FOR FDA SUBMISSION ONLY

PAGE 1

IQOS®

ENGLISH

CUSTOMER CARE

Call: 1-877-GET-IQOS
(1-877-438-4767)

Website: www.GetIQOS.com

LIMITED WARRANTY

Duration
The duration of this warranty, relevant to your country of purchase, is as follows:

United States	3 months

What this warranty covers
Philip Morris USA (PM USA) warrants the IQOS® hardware and accessories, including the pocket charger, holder, A/C power adapter and USB cable ("IQOS® System"), to function properly for three months from the original date of purchase.

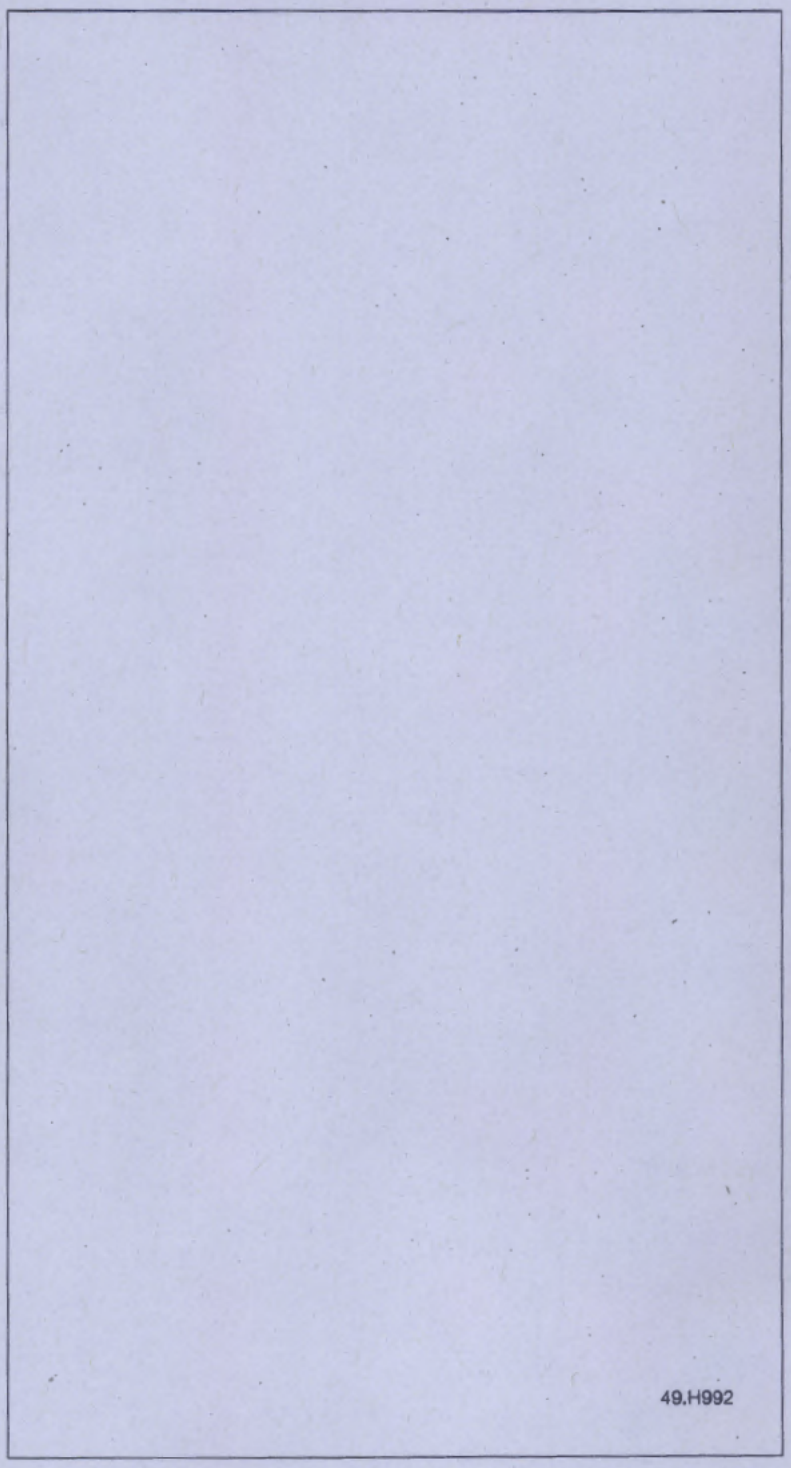
What is excluded from this warranty
This warranty does not apply to normal wear and tear, nor damage caused by accident or abuse. In addition, this warranty does not apply to: cosmetic damage after purchase (such as scratches, dents and broken plastic); damage to the IQOS® System caused by misuse, power surge, improper handling, liquid contact, fire, removal of serial number, or abnormal storage; negligence by you or by any third party; malfunction due to use with non-compatible product; damage or malfunction caused by an attempt to open, modify and/or repair an IQOS® System component, either by a user or by a technical provider not accredited by the manufacturer; or damage or malfunction caused by failure to use as described in the User Guide.

Information on how to make a claim
Please call 1-877-GET-IQOS (1-877-438-4767) or go to http://www.GetIQOS.com or visit an IQOS® store if you wish to make a warranty claim under this warranty.

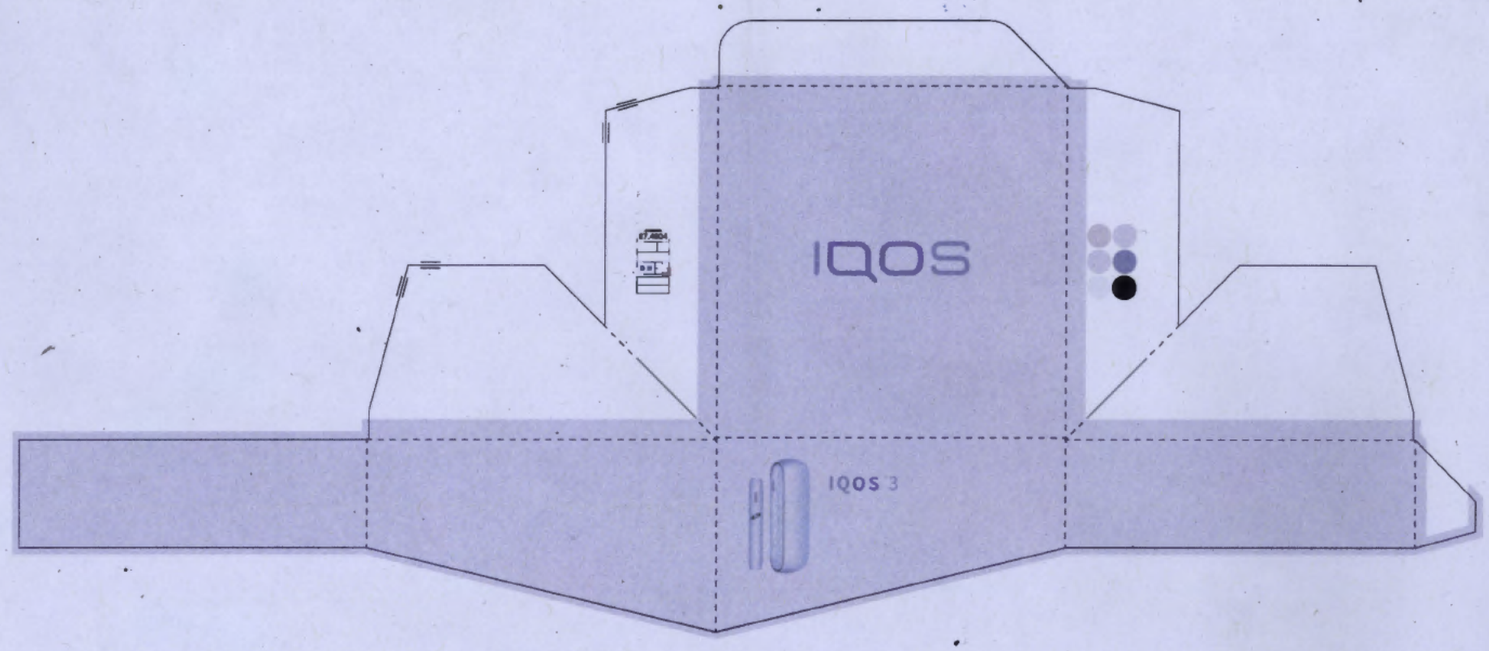
Keep a copy of your purchase receipt as proof of purchase. Be sure to register your product at the IQOS® store or http//www.GetIQOS.com.

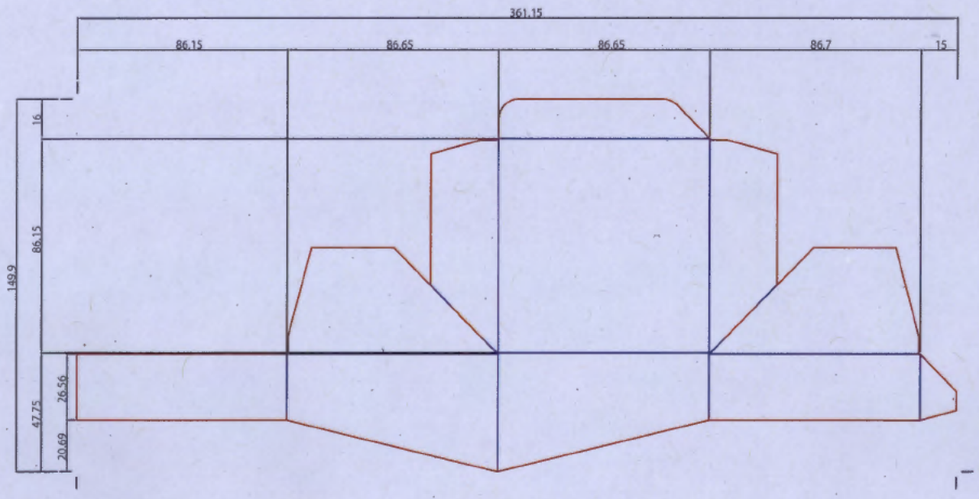
49.H992 – IQOS 3 US Warranty Card_FOR FDA SUBMISSION ONLY

PAGE 2

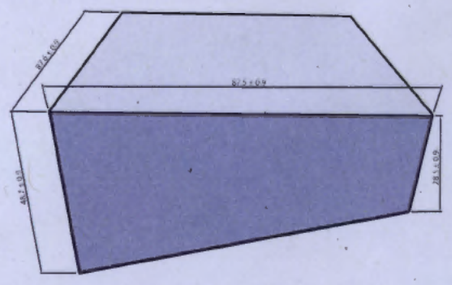


87.4604 – IQOS 3 HAT_FOR FDA SUBMISSION ONLY



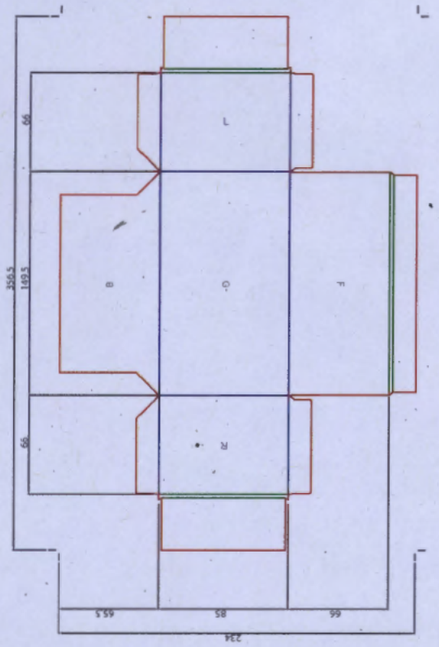


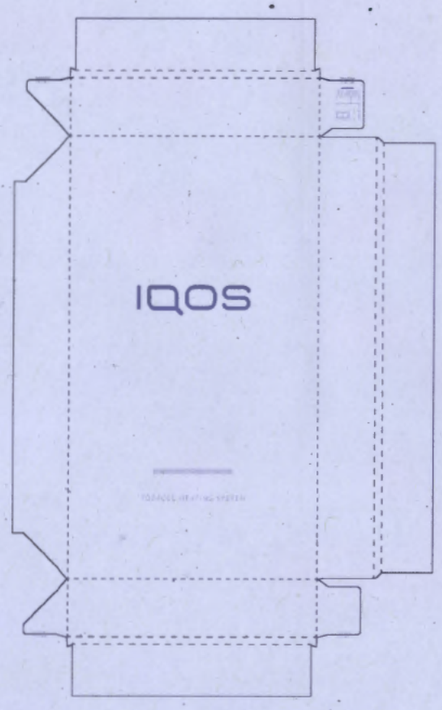
PRE-FORMED HAT

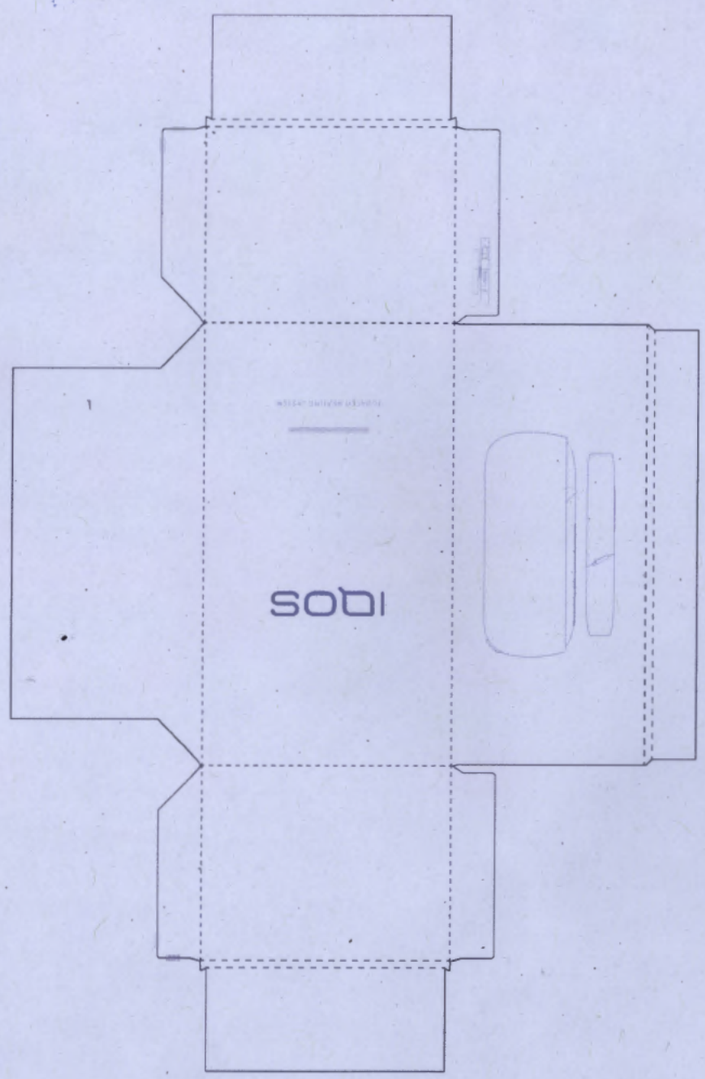


87.4605 – IQOS 3 BOX_FOR FDA SUBMISSION ONLY

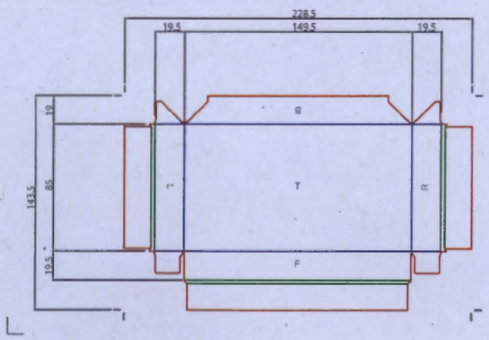
WRAPPING PAPER OF BASE







WRAPPING PAPER OF LID





PRE-FORMED BOX

Sender

Philip Morris Products SA
Santiago Lopez-Serrano
Quai Jeanrenaud 3
NEUCHATEL, 2000
Switzerland
Phone Nr.: +41582421705 Fax:
Tax ID/VAT No.: CHE116276488
EORI:

Proforma Invoice

Date: 2020-03-30 Waybill Number: 3545789096
Invoice Number: 0320-262

Exporter ID:
Exporter Code:

Receiver

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Document Control Center
Building 71, Room G335
SILVER SPRING, 20993
Maryland
United States of America
Phone Nr.: +13017969270 Fax:
Tax ID/VAT No.: Email:
EORI:

Bank Details

INN: OGRN:
KPP: OKPO:

Billed to

Phone Nr.: Fax:
Tax ID/VAT no:

Shipment Reference: 0320-262/PMP16590
Receiver Reference:

Other Remarks:

Full Description of Goods	Commodity Code	Qty	Unit Value	Sub-total Value	Net Weight	Gross Weight	Country of Origin
1 X USB FLASH DRIVE + PRINTED DOCUMENTS		1.00 PCS	21.00 CHF	21.00 CHF	0.200 kg	0.400 kg	SWITZERLA-ND

Total Goods Value:	21.00	Total Net Weight:	0.200 kg
Total line items:	1	Total Gross Weight:	0.400 kg
Number of pallets:	0	Currency code:	CHF
Total units:	1.0	Terms of Payment:	
Reason for Export:	Formal Export, Proforma	Payer of GST/VAT:	
Type of Export:	Permanent	Duty/taxes acct:Receiver Will Pay	
Terms of Trade:	Delivered at Place	Requiere Pedimento: No	
Other charges:	0.00	Duty/tax billing service:	
Freight cost (if paid by sender):	0.00	Carrier:	DHL
Insurance cost (if paid by sender):	0.00	Ultimate Consignee:	
Total Invoice Amount:	21.00	Exemption Citation:	

I/We hereby certify that the information contained in the invoice is true and correct and that the contents of this shipment are as stated above.

Signature: Company Stamp:

Sender

Philip Morris Products SA
Santiago Lopez-Serrano
Quai Jeanrenaud 3
NEUCHATEL, 2000
Switzerland
Phone Nr.: +41582421705 Fax:
Tax ID/VAT No.: CHE116276488
EORI:

Proforma Invoice

Date: 2020-03-30 Waybill Number: 3545789096
Invoice Number: 0320-262

Exporter ID:
Exporter Code:

Receiver

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Document Control Center
Building 71, Room G335
SILVER SPRING, 20993
Maryland
United States of America
Phone Nr.: +13017969270 Fax:
Tax ID/VAT No.: Email:
EORI:

Bank Details

INN: OGRN:
KPP: OKPO:

Billed to

Phone Nr.: Fax:
Tax ID/VAT no:

Shipment Reference: 0320-262/PMP16590
Receiver Reference:

Other Remarks:

Full Description of Goods	Commodity Code	Qty	Unit Value	Sub-total Value	Net Weight	Gross Weight	Country of Origin
1 X USB FLASH DRIVE + PRINTED DOCUMENTS		1.00 PCS	21.00 CHF	21.00 CHF	0.200 kg	0.400 kg	SWITZERLAND

Total Goods Value:	21.00	Total Net Weight:	0.200 kg
Total line items:	1	Total Gross Weight:	0.400 kg
Number of pallets:	0	Currency code:	CHF
Total units:	1.0	Terms of Payment:	
Reason for Export:	Formal Export, Proforma	Payer of GST/VAT:	
Type of Export:	Permanent	Duty/taxes acct:Receiver Will Pay	
Terms of Trade:	Delivered at Place	Requiere Pedimento: No	
Other charges:	0.00	Duty/tax billing service:	
Freight cost (if paid by sender):	0.00	Carrier:	DHL
Insurance cost (if paid by sender):	0.00	Ultimate Consignee:	
Total Invoice Amount:	21.00	Exemption Citation:	

I/We hereby certify that the information contained in the invoice is true and correct and that the contents of this shipment are as stated above.

Name: Signature: Company Stamp:

Sender

Philip Morris Products SA
Santiago Lopez-Serrano
Quai Jeanrenaud 3
NEUCHATEL, 2000
Switzerland
Phone Nr.: +41582421705 Fax:
Tax ID/VAT No.: CHE116276488
EORI:

Proforma Invoice

Date: 2020-03-30 Waybill Number: 3545789096
Invoice Number: 0320-262

Exporter ID:
Exporter Code:

Receiver

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Document Control Center
Building 71, Room G335
SILVER SPRING, 20993
Maryland
United States of America
Phone Nr.: +13017969270 Fax:
Tax ID/VAT No.: Email:
EORI:

Bank Details

INN: OGRN:
KPP: OKPO:

Billed to

Phone Nr.: Fax:
Tax ID/VAT no:

Shipment Reference: 0320-262/PMP16590
Receiver Reference:

Other Remarks:

Full Description of Goods	Commodity Code	Qty	Unit Value	Sub-total Value	Net Weight	Gross Weight	Country of Origin
1 X USB FLASH DRIVE + PRINTED DOCUMENTS		1.00 PCS	21.00 CHF	21.00 CHF	0.200 kg	0.400 kg	SWITZERLAND

Total Goods Value:	21.00	Total Net Weight:	0.200 kg
Total line items:	1	Total Gross Weight:	0.400 kg
Number of pallets:	0	Currency code:	CHF
Total units:	1.0	Terms of Payment:	
Reason for Export:	Formal Export, Proforma	Payer of GST/VAT:	
Type of Export:	Permanent	Duty/taxes acct:	Receiver Will Pay
Terms of Trade:	Delivered at Place	Requiere Pedimento:	No
Other charges:	0.00	Duty/tax billing service:	
Freight cost (if paid by sender):	0.00	Carrier:	DHL
Insurance cost (if paid by sender):	0.00	Ultimate Consignee:	
Total Invoice Amount:	21.00	Exemption Citation:	

I/We hereby certify that the information contained in the invoice is true and correct and that the contents of this shipment are as stated above.

Company Stamp:



EXPRESS WORLDWIDE WPX DHL

2020-03-30 MYDHL+ 1.0 / *30-0621*

From : Philip Morris Products SA
Santiago Lopez-Serrano
Quai Jeanrenaud 3

2000 NEUCHATEL
Switzerland

Origin:
GVA

To : Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Document Control Center
Building 71, Room G335
20993 SILVER SPRING Maryland
United States of America

Contact:
Center for Tobacco Products

B2 US-DCA-DCA

C

Day Time

Ref: 0320-262/PMP16590

Pce/Shpt Weight Piece
0.4 kg 1 / 1

Contents: 1 X USB FLASH D RIVE + PRINTED DOCUMENTS

WAYBILL 35 4578 9096

(2L)US20993+48000001

(J) JD01 4600 0076 9980 5059

Received
APR 01 2020
CTP Mailroom