User Manual

Smokeless XQuit App

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MD

Inhalt

1.   About the Smokeless XQuit app

Dear Customer,

Please read this user manual carefully to ensure the correct use of the app. Retain it for later use, make it available to other users and follow the instructions it contains.

With kind regards,

The Smokeless XQuit team.

2.   Intended Purpose

2.1.   Intended Purpose

The Smokeless XQuit App is a medical software to support smoking cessation. The current smoking habits are recorded in the app. Subsequently, the app supports smoking cessation by using methods of behavioural therapy.

2.2.   Indication

Smoking

2.3.   Patient population

The app is intended for smokers willing to quit with a minimum age of 18 years.

3. Explanation of symbols

Symbol	Explanation
	Manufacturer
	Follow the instructions in the user manual
CE	The product is governed by REGULATION (EU) 2017/745 MDR. The CE marking symbolises conformity to all the obligations incumbent on manufacturers for the product by virtue of the Community directives providing for its affixing.
	Date of manufacture
UDI	Unique Device Identifier
MD	Medical Device

4. Functionality

The medical app provides behavioural change therapy. Scientifically based concepts such as gamification, peer pressure and recognised drug-specific interventions are used for this purpose. The user goes through individual therapy tailored to their habits and smoking behaviour. Data on the smoking behaviour of the consumer is used for the individual therapy.

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5. System Requirements

The Smokeless XQuit app supports:

- iOS 11 and Android Version 7.0 or higher
- A smartphone with at least 300 MB of free space
- A web browser that supports HTML5, JavaScript and CSS
- Bluetooth and internet connection
- Optional: Smokeless XQuit inhaler or other compatible Bluetooth inhalers

6.　　Application

The Smokeless XQuit app is aimed at users who intend to quit smoking.

7.　　Type and duration of application

The application duration includes an assessment phase and a smoking behaviour reduction programme and takes place over a period of 90 days.

After you have quit smoking, you can continue to use the app if you need to remain smoke-free.

8.　　Frequency of use

You should use the app at least once a day during the smoking reduction programme. You can continue to use the app if necessary to stay smoke free.

9.　　Contraindications (when not to use the app)

- Those under the age of 18
- Pregnant or breastfeeding women
- If you connect the app to a compatible inhaler, please take note of the possible contraindications of the combined device.

10.　　Safety Instructions

- If you have any health concerns or you feel unwell in any way, please consult your GP.
- If the app does not work properly, or if you feel uncomfortable or are in pain, stop using the app it immediately.
- If you connect the app to a compatible inhaler, ensure you follow the instructions and safety or warning notices for the combined device.

11.　　Side Effects

At this point in time, there are no known side effects from using the app.

If you connect the app to a compatible inhaler, please take note of the possible side effects for the combined device.

12. Interactions

At this point in time, there are no know interactions from using the app.

If you connect the app to a compatible inhaler, please take note of the possible interactions with the combined device.

13. Minimum Age

The Smokeless XQuit app is aimed at patients aged 18 and over.

14. Software Version

The latest software version of the app can be found in the side menu in the Smokeless App.

15. Sales and technical support

If you have any technical questions, please contact:

Smokeless.world GmbH

Schlossstrasse 19

82031 Grünwald

www.help.smokeless.world

support@smokeless.world

16. Manufacturer

	NEXTEC medical GmbH Zöllinplatz 4 D-79410 Badenweiler www.nextec-medical.com

17. Information last updated on:

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