

EC Declaration of conformity

Hebei Houde Hanfang Medical Devices Group Co., Ltd.

Beisun Village, Zhengding County, Shijiazhuang City, Hebei Province, China

We declare that the following product :

HEALTH PATCH

Model:

3X3CM,3.5X3.5CM,3.8X7.5CM,4.3X16CM,5X5CM,5X7CM,4X11CM,5X12CM,5X7.5CM,5.5X10CM,5.5X9.5CM,6.5X9.5CM,4.5X8.5CM,6.5X19CM,6.61X.9CM,5.5X1.6CM,4.5X1.5CM,7X10CM,7.5X11CM,7X9CM ,8X10CM,7.5X7.5CM,6X7CM,7.6X2.9CM,5X6.7CM,6X13CM,7.5X9.5CM,6.3X12CM,7.6X11CM,8X11CM,8.5X4.5CM,9.5X5.5CM,9X9CM,10X15CM,11X18CM,10X10CM,10X14CM,10X13CM,10X12CM,12X6.5CM ,12.5X11.5CM,15X35CM,20X31CM,20.5X23CM,6X9CM,6X7CM,4X15CM,4.5X7.5CM,4.5X15CM,3.5X7.5CM,3.5X15CM,9X3.8CM, 8X3.5CM, 8.5X3.5CM, Φ 3CM, Φ 6CM, Φ 10CM

Described above is in conformity with the following directive (s) :

**Verification of the presence of Technical
Documentation compatible with the Medical
Devices Regulation 2017/745 Annex I**

Relevant standard (s):

EN ISO 14971:2019 Medical devices. Application of risk management to medical devices

EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices

EN ISO 10993-1:2020 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process

The reference of the File identified with the No:

TST202111Q2165-1SR

And we are aware about the contents and information included in the ModCC04.06.1 regulation that is considered totally accepted.

Date of issue

2021.11.18

Stamp and Signature of authorized personnel

