

# Europe aims for a paper-free future



## Digital Instructions for Use- FAQ

### 1. What are IFUs and why are they important?

IFUs are "instructions for use". These paper documents provide detailed guidance on how to use a product or device safely and effectively. IFUs are important because:

- They provide clear instructions for correct understanding of product markings and usage to ensure desired outcomes
- They outline safety steps to prevent accidents, injuries, or misuse
- Some industries such as the medical industry require IFUs for legal compliance
- Thorough IFUs mitigate manufacturer liability by informing users effectively

### 2. Why are paper IFUs being removed from Ansell packaging in Europe?

Ansell's been advocating for the removal of paper IFUs since 2021 because it reduces packaging's impact on the environment. We can now make this happen in Europe as a result of:

1. The EU Commission's approval of the use of paperless IFUs,
2. The development of a good practice guide from European Safety Federation (ESF), which outlines the conditions whereby manufacturers can now remove paper IFUs if QR codes on the package link to product webpages providing digital IFUs.

### 3. What are the environmental benefits of getting rid of paper IFUs and moving to digital?

Ansell supports the switch to digital IFUs as it could save at least 45,000 tonnes\* of paper every year across the EU – great news for the environment and a big step forward in PPE's digital transformation. Making PPE packaging in Europe more sustainable also helps our customers meet their own sustainability goals.

### 4. How does this change affect the availability of product information?

QR codes on products or packages will improve the availability of product information by providing access to easy-to-read digital versions of IFUs on product webpages.

### 5. What measures are being taken to ensure compliance in specific regions?

Paper IFUs will continue to be provided for products sold in Saudi Arabia and UAE, in compliance with regional regulations.

### 6. Are there exceptions to the removal of paper IFUs?

Certain products, such as those certified by the National Fire Protection Association (NFPA) in the U.S, may still require paper IFUs.

\*Reference: Minutes Meeting of the Commission Expert Group on Personal Protective Equipment (1), 4 May 2023, Brussels and the European Safety Federation's position paper.

## Thinking of people and planet first.

For over 130 years, Ansell has been protecting people, and our ambitions today are stronger than ever. By setting ourselves ambitious goals on protecting our environment, we seek to break new ground. With increased sustainability and ever smarter, more connected PPE, we strive to ensure the safety of workers and the environment we live in.

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### 7. When will Ansell stop including paper IFUs in their product shipping cases?

Our intention is to remove paper IFU's from our products as they become compliant with the new rules. This will likely happen beginning in November 2024. Before removing the paper IFU from the shipper, we will ensure that:

- QR codes and a weblink are added to our products or first packaging
- IFU's are downloadable from our website per separate language
- Specific generic IFU's are available via a QR code for online purchases

Our aim is to finish this process by July 2025.

### 8. What if specific EU Member States still impose the need for paper IFUs?

Ansell IFUs will always be available and easily accessible for printing in the relevant language through our weblink. If required, we will also make paper IFUs available upon request, free of charge.

Additionally, it will be Ansell's responsibility to take any responsibility and liability in case objections would be expressed by the applicable Member State. Furthermore, Ansell will continue to liaise with the relevant Member States and with the Commission to ensure full acceptance of digital IFUs.

### 9. As a distributor of Ansell products, I'm required to comply with Regulation 2016/425, which mandates that I must provide paper IFUs to customers. How will Ansell support us in meeting this requirement, and what steps are being taken to ensure compliance with this regulation?

Ansell will ensure that all products comply with the new regulation before we remove paper IFU's from our products. In cases where a distributor is opening up our packaging to sell products in smaller units, however, they will continue to be responsible as they have been in the past for ensuring either a paper IFU, a sticker with the text of the IFU in the relevant local language, or a sticker with a QR code pointing to an online IFU is present on the packaging of the smaller quantities of product being sold. It still remains the distributor's responsibility to add a copy of the IFU with the PPE, if products are sold in smaller quantities to the end-user, like this was always the case in the past.

### 10. What is the advantage of switching to digital IFU's for Ansell and other stakeholders?

Next to the environmental benefits, digital IFU's can be updated much quicker and will also make it possible to often access them at any time versus paper IFUs that typically get disposed before the PPE gets used.

It will also make it easier for enforcement authorities to access and check the IFUs at any time or place.

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