

Object: Important information on the VYGON Enteral Nutrition range:

Application of the ISO standard 80369-3 ENFit.

Dear customers,

As you know, Vygon has been very involved for many years in the enteral nutrition market. Now, the evolution of the enteral nutrition connection to a standardised device is a matter of all our customers.

This new connection, named ENFit™, corresponds to the ISO standard 80369-3. It is not yet published; it will probably be on 2016 February.

Vygon will also launch in agreement with a GEDSA planning (Global Enteral Device Suppliers Association) a complete range named Nutrifit® corresponding to the ISO standard 80369-3 ENFit™.

The Vygon range Nutrifit® will propose, for all products impacted by the standard:

- Administration set for pumps of enteral nutrition
- Feeding tubes
- Accessories
- Syringes

The arrival of our Nutrifit® products on the market is expected for 2016 March.

However in order to meet the specific needs of neonates as is highlighted in the ISO standard, we will keep our Nutrisafe2 range.

Extract of the ISO/DIS 80369-3.2 – Annex A - § Subpopulation:

« Concerns have been raised about the possible risks of delivering accurate doses of medicines in certain clinical practices across high risk subpopulations (e.g. neonatal patients) when using a reversed connection system (female to male). This orientation may introduce inadvertent displacement of fluid originally contained within the female SMALL-BORE CONNECTOR. This displacement occurs when fluid is drawn up into the syringe without the use of an adaptor or drawing-up device which is then administered through a CONNECTION being made to a feeding tube. Laboratory testing has demonstrated that the majority of this fluid is displaced into the male SMALL-BORE CONNECTOR and the device behind it. »

Vygon will therefore offer an entirely safe and secure enteral nutrition range from neonatology to adults. Nutrifit® is specifically dedicated to adults and pediatrics, and Nutrisafe2 to neonates and premature babies.

For further information, please contact questions@vygon.com



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