Document Number: PRO-06-008

Revision: 06



Matrix Park, 1 Western Avenue, Buckshaw Village, Chorley PR7 7NB T: +44 (0) 1772 299 900 F: +44 (0) 1772 299 901

PRODUCT SPECIFICATION

| Product Range | | | AZO™ | | | | |
|--|---|------------------------|--|-----------|---------------|---|--|
| Product Name | | | AZOMAX® | | | | |
| Product Code | Product Description | 1 | Size / Di Tolerand | | ons / | Material / Composition / Active Ingredients | |
| AM200WCE | AZOMAX® Cleaning a disinfection wipes for u non-invasion medical de | nd n se on /e | 200mm 180mm | ± 5 mr | | 25gsm 100% Polypropylene Active ingredients: Didecyl Dimethyl Ammonium Chloride Polyhexamethylene Biguanide Alkyl Dimethyl Benzyl Ammonium Chloride | |
| Intended Use | | | Cleaning and disinfectant wipes for use on non-invasive medical devices | | | | |
| Classification | | | Medical Device Class IIa Rule 15 | | | | |
| Product/Device Single Use | | | Yes – individual wipes are single use | | | | |
| Components Latex Free | | | Yes | | | | |
| Shelf Life | | | 24 months from date of manufacture | | | | |
| Storage | | | Store in a cool, well ventilated area; keep container tightly closed | | | | |
| Sterilisation Method | | | N/A | | | | |
| Special Instruc | tions | William I | | | | | |
| Refer to MSDS | for safety in | ormatio | on | | | | |
| Pack Qty, Carton Qty, Case Q Pack/Pouch content Weight, Q | | | | | et Dime | nsions | |
| Per pack: 200 wipes Per case: 12 canisters Pack weight: 830g Case weight: 10kg | | | | | 200 x 1000mm | | |
| | | | nfiguration | | Pallet Weight | | |
| 4-WAY STD Cases Layers | | s per p | per layer: 6 per pallet: 5 ty per pallet: 30 | | 301Kg approx | | |
| Packaging Info | | Size | Home E.S. | | | | |
| Primary packaging | | | Secondary Packagin | | | Tertiary Packaging | |
| High density white | | | Cardboard case | | | Standard pallet with corner posts | |
| polyethylene canister, PET metal foil seal, white | | | Case dimensions: 44 335 x 260mm | | 13 x | | |
| polypropylene lid with a | | | | | | | |
| 6mm aperture for wipe | | | | | | | |
| dispensing. Canister | | | | | | | |
| dimensions 240 x 110mm | | | | | | | |
| Labelling Speci | | AL 10 100 | To the same | Nichaul I | | | |
| Primary (inner) | | A PERM | The Control of the Co | | | Back The solution AVE TO THE STREET | |
| Product REF, p | roduct name | . produ | ct descript | tion. m | anufac | turer name & address & symbol, expiry date & | |

Product REF, product name, product description, manufacturer name & address & symbol, expiry date & symbol, LOT number & symbol, storage instructions, pack quantity, active ingredients, barcode, 'do not flush' logo, 'do not macerate' logo, Made in Britain logo, artwork 'IC' reference, Instructions for use, CE symbol.

Document Number: PRO-06-008

Revision: 06



Matrix Park, 1 Western Avenue, Buckshaw Village, Chorley PR7 7NB T: +44 (0) 1772 299 900 F: +44 (0) 1772 299 901

| Secondary (middle): | | | | | | | | |
|---|----------------|--|--|--|--|--|--|--|
| Product REF, product name, product description, manufacturer name & address & symbol, expiry date & symbol, LOT number & symbol, keep away from sunlight symbol, keep dry symbol, Barcode containing: | | | | | | | | |
| (240) product reference (10) LOT number (17) expiry date, "Made in the U.K.", artwork 'IC' reference, CE | | | | | | | | |
| symbol. | | | | | | | | |
| | | | | | | | | |
| Tertiary (outer): | | | | | | | | |
| N/A | | | | | | | | |
| Standards of Compliance | | | | | | | | |
| ISO 9001 | | | | | | | | |
| ISO 13485 | | | | | | | | |
| Medical Device Directive 93/42/EEC | | | | | | | | |
| Approval – Vernacare Limited | | | | | | | | |
| Marketing | | | | | | | | |
| Name DAUID NEULUE | Signed | | | | | | | |
| Position Maguer MANAGER | Date S/8/17 | | | | | | | |
| Quality | | | | | | | | |
| Name Down Howes | Signed | | | | | | | |
| Position lead Quarry exercises | Date 10 sep 18 | | | | | | | |